

EPA Reg. No. 524-522
Vol. 2



524-522

Vol 2 of 2



009271101

UNIT STATES ENVIRONMENTAL PROTECTIC AGENCY

AUG 01 2007

Dr. James C. Jennings
 Cotton & Specialty Crops Team Lead
 U.S. Biotechnology Regulatory Affairs
 Monsanto Company
 800 North Lindbergh Blvd
 St. Louis, MO 63167

Dear Dr. Jennings:

Subject: Your Letter of June 29, 2007 Requesting Clarification of BollGard II Cotton
 Conditions of Registration
 EPA Registration No. 524-522

Since most of the Bollgard II cotton was planted before the natural refuge option was approved by EPA, Monsanto must survey growers and report IRM compliance for 2007 in areas that now are able to utilize the natural refuge option. Subsequently, Monsanto is not required to survey growers or report IRM compliance in natural refuge areas, as specified in the registration.

Plantings of Bollgard II cotton after the natural refuge option was approved (June 1, 2007), which are in natural refuge areas as specified in the registration, may be planted with natural refuge.

Sincerely,



Sheryl Reilly, Ph.D. Chief
 Microbial Pesticide Branch
 Biopesticides and Pollution
 Prevention Division (7511P)

CONCURRENCES

SYMBOL	7511P	7511P						
SURNAME	Reilly	Reilly						
DATE	8/1/07	8/1/07						

MONSANTO



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

June 29, 2007

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Biopesticide and Pollution Prevention Division

Subject: Monsanto Company requests clarification on Bollgard II[®] cotton conditions of registration dated June 1, 2007 (EPA Reg. No. 524-522).

Dear Dr. Reilly:

On June 1, 2007, EPA granted a Bollgard II cotton registration (EPA Reg. No. 524-522) that allows a natural refuge option in specified geographical regions of the U.S. Monsanto Company requests clarification on the following conditions of the registration:

- Page 2, Section 4.d.
Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.
- Page 6, Section 5.d.4.
Monsanto shall continue to implement an ongoing, approved IRM compliance assurance program in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. The program is designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Bollgard II[®] cotton product.

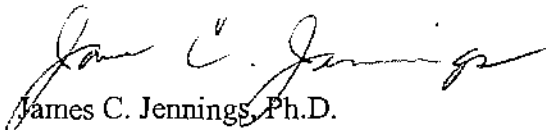
[®] Bollgard II is a registered trademark of Monsanto Technology LLC.

Specifically, Monsanto requests clarification regarding the 2007 IRM compliance assurance report that will be submitted to EPA in January 2008. It is Monsanto's understanding that we would report compliance for the areas listed in sections 4.d and 5.d.4 of the registration, but would not survey growers or report IRM compliance for 2007 in natural refuge areas as specified in the registration.

Additionally, please confirm that growers who planted or replanted with Bollgard II cotton on or after June 1, 2007, and are in natural refuge areas as specified in the registration are able to utilize the natural refuge option.

Thank you. Please contact me at 314-694-6098 or Dr. Russell Schneider at 202-383-2866 if you have any questions regarding this request.

Sincerely,



James C. Jennings, Ph.D.
Cotton & Specialty Crops Team Lead
U.S. Biotechnology Regulatory Affairs

cc: Alan Reynolds
Melinda McCann
Russell Schneider

Receipt for Section 3			
S: 821044		Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No	
Regulatory Type: Product Registration - Section 3		Fee-Free Service: <input type="radio"/> Yes <input checked="" type="radio"/> No	
Application Type: Miscellaneous Receipt		Billable: <input type="radio"/> Yes <input checked="" type="radio"/> No	
Company: 524 MONSANTO COMPANY		V	
Risk Manager: Biologicals & Pollution Prevention Division PM Team 92			
Product #: 524-522		Product Name: BOLLGARD II COTTON	
Override: <input type="text"/>			
Me Too Section3: <input type="text"/>		Me Too Product Name: <input type="text"/>	
Application Date: 07-Dec-2007 <input checked="" type="checkbox"/>		OPP Rec'd Date: 10-Dec-2007 <input checked="" type="checkbox"/>	
Front End Date: 10-Dec-2007 <input checked="" type="checkbox"/>		Risk Manager Send Date: 10-Dec-2007 <input checked="" type="checkbox"/>	
FFS Due Date: <input type="text"/>		Negotiated Due Date: <input type="text"/>	
OPP Target Date: <input type="text"/>			
Fast Track: <input type="checkbox"/>		New Ingredient: <input type="checkbox"/>	
Receipt Description:			
data required as a condition of registration		New Ingredient Request Date: <input type="text"/>	
		New Ingredient Received Date: <input type="text"/>	
Form A: <input type="checkbox"/>		Form B: <input type="checkbox"/>	
Signature Date: <input type="text"/>		Signature Date: <input type="text"/>	

Print Letter
 Enter More Information
 Tracking

rec'd 12/31/07

routed to Jeannette M via DP 347933



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

December 7, 2007

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Biopesticide and Pollution Control Division

Subject: Submission of a report entitled "Susceptibility of Pink Bollworm to Bt Toxins Cry1Ac and Cry2Ab2 in the Southwestern U.S.A. in 2006," as a condition of the registrations of Bollgard® and Bollgard II® cotton (EPA Reg. Nos. 524-478 and 524-522).

Dear Dr. Reilly:

As a condition of the June 23, 2006 registration of Bollgard cotton and the June 1, 2007 registration of Bollgard II cotton (EPA Reg. Nos. 524-478 and 524-522), Monsanto is required to submit annually a report on results of pink bollworm susceptibility monitoring. The purpose of the monitoring is to assess potential emergence of resistance to Cry1Ac and Cry2Ab2 proteins.

Enclosed find a report prepared by Dr. Timothy Dennehy and coworkers at The University of Arizona and colleagues at the Arizona Cotton Research and Protection Council, which fulfills this condition of registration.

Dr. Dennehy and his colleagues have been monitoring Arizona populations of pink bollworm susceptibility to Cry1Ac since 1997, and Cry2Ab2 since 2001. In 2006, a total of 15 strains of pink bollworm were collected from cotton fields in Arizona and California. These strains were cultured in the laboratory and tested for susceptibility to Cry1Ac and Cry2Ab2 using diagnostic concentrations of 1.0 and 10 µg protein/mL of diet. The report states that there is no indication of pink bollworm resistance development to Cry1Ac or Cry2Ab2 at the locations sampled in 2006. Additionally, the report states that in 2006, Bt cotton continued to exhibit exceptional field performance both within and outside of the pink bollworm eradication zone in Arizona.

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Please find enclosed copies of the following documents:

- Transmittal document
- Application for Pesticide (EPA Form 8570-1)
- Volume 1 of 1: Report entitled: "Susceptibility of Pink Bollworm to Bt Toxins Cry1Ac and Cry2Ab2 in the Southwestern U.S.A. in 2006" (three copies)

Please contact Dr. Russell Schneider at 202-383-2866 or me at 314-694-7556 if you have any questions regarding this report.

Sincerely,



Melinda C. McCann
Cotton Regulatory Affairs Manager

Enclosures

cc: Alan Reynolds
Russell Schneider

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

**REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS
SUBMITTED**

EPA Reg. Nos. 524-478 and 524-522

Submission of a report entitled "Susceptibility of Pink Bollworm to Bt Toxins Cry1Ac and Cry2Ab2 in the Southwestern U.S.A. in 2006," as a condition of the registrations of Bollgard® and Bollgard II® cotton.

TRANSMITTAL DATE

December 7, 2007

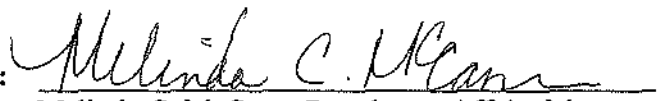
LIST OF SUBMITTED DOCUMENTS

Volume 1: Dennehy, T.J., G.C. Unnithan, V. Harpold, Y. Carrière, B. Tabashnik, L. Antilla, and M. Whitlow. 2007. Susceptibility of Pink Bollworm to Bt Toxins Cry1Ac and Cry2Ab2 in the Southwestern U.S.A. in 2006. 04-CT-133E-36 and 04-CT-134E-36. An unpublished report written by researchers at The University of Arizona and Arizona Cotton Research & Protection Council.

MRID Number 47288901

COMPANY NAME: Monsanto Company

COMPANY OFFICIAL:


Melinda C. McCann, Regulatory Affairs Manager

DATE: December 7, 2007

COMPANY CONTACT: Dr. Russell Schneider (202) 383-2866

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier
Number

Application for Pesticide – Section I

t. Company/Product Number EPA Reg. Nos. 524-478 and 524-522*	2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Bollgard® and Bollgard II® Cotton	PM # 92	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 N. Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of Bollgard and Bollgard II cotton report entitled: "Susceptibility of Pink Bollworm to Bt Toxins Cry1Ac and Cry2Ab2 in the Southwestern U.S.A. in 2006."

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No * Certification must be submitted	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per Container	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify)		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled				<input checked="" type="checkbox"/> Other _____	

Section – IV

f. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Russell P. Schneider, Ph.D.		Title Director, Regulatory Affairs		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Cotton Regulatory Affairs Manager			
4. Typed Name Melinda C. McCann (314) 694-7556		5. Date December 7, 2007			

EPA Form 8570-1 (Rev. 3-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

MONSANTO
imagine



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

November 26, 2007

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Biopesticide and Pollution Prevention Division

Subject: Monsanto requests an extension of the reporting of 2007 tobacco budworm collections and natural refuge modeling for the Bollgard II® cotton registration (EPA Reg. No. 524-522).

Dear Dr. Reilly:

As a condition of the June 1, 2007 registration for Bollgard II cotton Monsanto is required to submit gossypol and natural refuge modeling data on tobacco budworms collected from west Texas, Alabama, and Tennessee. Due to late shipments of moths to the analytical lab, Monsanto requests an extension of the reporting date from January 31, 2008 to March 31, 2008.

Please contact Dr. Russell Schneider at 202-383-2460 or me at 314-694-7556, if you have any questions regarding this request.

Sincerely,

Melinda C. McCann
Cotton Regulatory Affairs Manager

cc: Alan Reynolds
Russell Schneider

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DEC 18 2007

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 5820919 | 1300

Melinda C. McCann
 Cotton Regulatory Affairs Manager
 Monsanto Company
 800 North Lindbergh Blvd.
 St. Louis, Missouri 63167

Subject: Bollgard II® Cotton
 EPA Reg. No. 524-522
 Request for Due Date Extension for 2007 Reports
 Your Correspondence of November 26, 2007

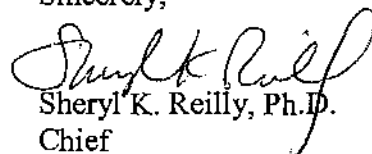
Dear Ms. McCann:

On November 26, 2007, you wrote to request that the January 31, 2008 due date for submission of the west Texas, Alabama and Tennessee gossypol and natural refuge modeling data on tobacco budworms be extended until March 31, 2008. Your letter indicated that the additional time is needed because the moth shipments arrived late at the laboratory.

By this letter, I grant your request. The new submission due date for the reports described above is March 31, 2008.

Should you have questions or concerns regarding this letter, please contact me or Denise Greenway, of my staff, via greenway.denise@epa.gov or (703) 308-8263.

Sincerely,



Sheryl K. Reilly, Ph.D.

Chief

Microbial Pesticides Branch

Biopesticides and Pollution

Prevention Division (7511P)

DGreenway/308-8263/12-17-07/524-522extnreq.doc

CONCURRENCES

SYMBOL	7511P	7511P	7511P					
SURNAME	Greenway	Reynolds	Reilly					
DATE	12/17/2007	12/18/07	12/18/07					

ROUTING AND TRANSMITTAL SLIP

Date

12/17/2007

TO: (Name, office symbol, room number, building, Agency)

1. Alan, please concur or comment

AR 12/18

2. Sheryl, please comment or sign

SK 12/18

3.

4.

5.

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	X Signature
Coordination	Justify	

REMARKS

Re: Bollgard II Cotton
Letter Granting Monsanto's Request for Additional Time
To Submit Certain TBW Reports for 2007

The moths arrived late at the lab, prompting this request to extend the 1/31/08 submission due date until 3/31/08.

This draft letter grants the request.

Please direct any concerns to me. Thanks.

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions.

FROM: (Name, org. symbol, Agency/Post)

Denise Greenway

Denise

Room No.—
Bldg.

PY 8951

Phone No.
308-8263

Denise - do you want the original to have the file name or the copy?

Sheryl-

Thanks for catching my printer error. I hope you will sign this corrected white copy.

Denise

12/19/07

Thank you!

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 524-522

Send to SIG: check box ☒

This material is:

- ☒ New stamped-accepted label
- ☐ New CSF
- ☐ Notification
- ☐ Final Printed Label
- ☐ Other: _____

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Mike Mendelsohn

Phone: 308-8715 Division: ARD

Date: 7/12/07

**U.S. ENVIRONMENTAL PROTECTION AGENCY**

Office of Pesticide Programs
Biopesticides and Pollution
Prevention Division (7511P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

524-522

Date of Issuance:

6/1/07

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance: **Unconditional**

Name of Pesticide Product: Bollgard II Cotton

Name and Address of Registrant (include ZIP Code):

Monsanto Company
800 North Lindbergh Blvd
St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. The following information regarding commercial production must be included in the grower guide for Bollgard II® cotton and is a term of this registration:
 - a) No planting or sale for commercial planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
 - b) No planting or sale for commercial planting of Bollgard II cotton is permitted in Hawaii, Puerto Rico, and the U.S. Virgin Islands.
 - c) No planting or sale for commercial planting of Bollgard II cotton is permitted in the following counties in the Texas panhandle: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

Signature of Approving Official:

JZH see last page

Date:

6/1/07

3. The following information regarding test plots and seed production must occur on bags of Bollgard II cotton intended for these purposes and is a term of this registration:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

4. Insect Resistance Management Program Elements. The required IRM program for Bollgard II cotton must have the following elements:

- a. Requirements for a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- b. Requirements for Monsanto to prepare and require Bollgard II cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the IRM requirements;
- c. Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- d. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- e. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1Ac and Cry2Ab2 proteins in the target insects;

f. Requirements for Monsanto to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

g. Requirements for annual reports on or before January 31st each year for compliance assurance (including grower education) and sales. The tobacco budworm and cotton bollworm annual resistance monitoring reports must be submitted to EPA on or before June 30th each year and for pink bollworm, the annual resistance monitoring report must be submitted to EPA on or before December 31st each year. See Annual Reports section below.

5. Insect Resistance Management Requirements

- a. **Refuge Requirements for Pink Bollworm Resistance Management only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.**

All growers of Bollgard II® cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of Bollgard II® cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Btk* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt*

cotton refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard II cotton.

b. Natural Refuge Requirements for Tobacco Budworm and Cotton Bollworm Resistance Management only in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas (excluding the following counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler), and Virginia.

1) Tobacco budworm sampling must be conducted for at least one year in west Texas, Alabama, and Tennessee. An appropriate gossypol analysis, statistical analysis, calculation of effective and natural refuge, and simulation modeling must be performed to determine the likelihood of tobacco budworm resistance to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II® cotton using natural refuge. Previously, these states had only a single year of sampling data and analysis to support the natural refuge. The new data collected in 2007 and/or 2008 must be compared with previously collected data (2004 to 2006, depending on the location) to confirm the effectiveness of a natural refuge.

A report of these findings must be submitted to EPA on or before January 31st following the year of collection.

2) Monsanto must submit data to EPA by January 31st, 2012, and every five years thereafter, to support an EPA reassessment of the natural refuge and to confirm its effectiveness with tobacco budworm and cotton bollworm. The data must include: resistance monitoring data, cropping pattern analysis, and simulation modeling to reexamine levels of effective refuge in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Both cropping and land use patterns can change over time, which could impact the amount of natural refuge available to tobacco budworm and cotton bollworm relative to cotton. If based on this reassessment, EPA determines that additional tobacco budworm and/or cotton bollworm sampling, gossypol analysis, statistical analysis, and simulation modeling are needed to justify continuation of the natural refuge, Monsanto must submit these data within the EPA requested timeframe. If EPA's assessment concludes that the natural refuge is no longer scientifically supported, Monsanto has agreed and must submit an application to amend the registration to restore the structured refuge requirements previously required for tobacco budworm and cotton bollworm uses.

- 3) It is recommended that Monsanto develop a more complex, spatial model of resistance for Bollgard II cotton that further considers the evolution of resistance "hotspots" (i.e. localized areas of resistance) and provide EPA with this information. Key issues like spatial structure, linkage disequilibrium, and differential movement of males and females have not yet been explored in detail for pyramided Bt proteins. Such models would be more desirable to examine the resistance evolution at the local level where natural refuge may be limited for one or more generations of tobacco budworm.

c. Grower Agreements

While Monsanto will have flexibility to design its program to fit its own business practices, the registration is specifically conditioned on meeting the following requirements.

- 1) Persons purchasing the Bollgard II cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

- 3) Monsanto must continue to implement an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

- 4) Monsanto must continue to use an approved grower agreement. If Monsanto wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this registration.

- 5) Monsanto must continue an approved system which is reasonably likely to assure that persons purchasing the Bollgard II cotton sign grower agreement(s).

- 6) Monsanto shall maintain records of all Bollgard II cotton grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

- 7) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of the Bollgard II cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior October through September.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

d. IRM Education and IRM Compliance Monitoring Programs

Monsanto must implement the following IRM education and compliance monitoring programs:

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bollgard II cotton users the importance of complying with the IRM program. The program shall include information encouraging Bollgard II cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bollgard II cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each Bollgard II® cotton grower separate from the grower agreement. Monsanto shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Annually, Monsanto shall provide a report to EPA any substantive changes to the grower education activities as a part of the overall IRM compliance assurance program report.

4) Monsanto shall continue to implement an ongoing, approved IRM compliance assurance program in the states of Arizona, California, and New Mexico and in the following Texas Counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. The program is designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Bollgard II® cotton product. Other required features of the program are described in paragraphs 5 - 12 below.

5) Monsanto shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bollgard II cotton for an

individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bollgard II cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year. Monsanto shall confer with EPA on the design and content of the survey prior to its implementation.

7) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto will confer with the Agency prior to adopting any changes.

8) Monsanto must conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with Bollgard II® cotton growers to perform assessments of compliance with IRM requirements. There is no minimum cotton acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

9) Monsanto shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

10) If a grower, who purchases Bollgard II cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

11) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto, the number of tips investigated, the percent of growers who were not complying with the IRM requirements, and the follow-up actions taken.

12) Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

e. Insect Resistance Monitoring.

Monsanto must conduct an annual resistance monitoring program for *Heliothis virescens* (tobacco budworm) *Helicoverpa zea* (cotton bollworm), and *Gossypiella pectinophora* (pink bollworm) for the Cry1Ac and Cry2Ab2 toxins expressed in Bollgard II cotton as early as possible. Resistance monitoring programs must include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following terms and conditions:

- 1) Monsanto must submit a revised Bollgard II cotton (Cry2Ab2 and Cry1Ac toxins) resistance monitoring plan for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm) to EPA by September 1, 2007. A revised resistance monitoring plan approved by EPA must be used beginning in the 2008 growing season. The monitoring program must include increased sampling for tobacco budworm and cotton bollworm in the areas that have the greatest variability and potentially lowest levels of effective natural refuge. Sampling efforts should include all of the "worst-case" counties identified in Monsanto's 2004 to 2006 analyses of natural refuge in the states of Texas, Tennessee, Mississippi, Louisiana, Arkansas, Alabama, Georgia, and North Carolina. BPPD believes that resistance monitoring for tobacco budworm and cotton bollworm resistance to Cry1Ac and Cry2Ab2 will have added importance with adoption of a natural refuge as a resistance management strategy.
- 2) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest.
- 3) The following testing scheme for survivors of the diagnostic or discriminating concentrations (or identified survivors of any resistance detection method) must be implemented: 1) Determine if the observed effect is heritable; 2) Determine if the increased tolerance can be observed in the field (i.e., survive on Bollgard II® cotton plants); 3) Determine if the effect is due to resistance, 4) Determine the nature of resistance (dominant, recessive), 5) Determine the resistance allele frequency, 6) Determine, in subsequent years, whether the resistance allele frequency is increasing, and 7) Determine the geographic extent of the resistance allele (or alleles) distribution. Should the resistance allele frequency be increasing and spreading, a specific remedial action plan should be designed to mitigate the extent of Bt resistance. See section f. ("Remedial Action Plans") below.

- 4) Monsanto must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, cotton leafperforator and European corn borer. Monsanto will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto will investigate all damage reports. See Remedial Action Plans section below.
- 5) Monsanto must provide to EPA for review and approval any revisions to the tobacco budworm, cotton bollworm, and pink bollworm resistance monitoring plans prior to their implementation.
- 6) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

f. Remedial Action Plans

Specific remedial action plans are required for Bollgard II® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial (Mitigation) Action Plan for Tobacco Budworm and Cotton Bollworm (Attachment I)

If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto must implement the Remedial Action Plan approved by EPA. Monsanto must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

2) Remedial Action Plan for Pink Bollworm (Attachment II)

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto must implement the Arizona *Bt* Cotton Working Group's Remedial Action Plan. Monsanto must obtain approval from EPA before modifying the Arizona *Bt* Cotton Working Group's Remedial Action Strategy.

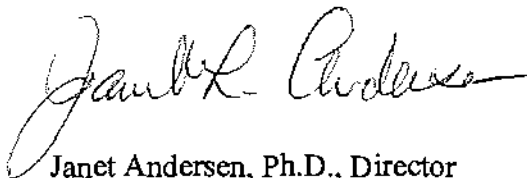
g. Annual Reports for Sales, Grower Education, Compliance Assurance, Grower Agreements, and Resistance Monitoring.

Annually by January 31st, Monsanto will provide EPA a report that contains the following information: number of units of the Bollgard II® cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements, results of the compliance assurance program including any substantive changes to the grower education program, and a sales report. The annual sales report should contain a summary of all Bollgard II cotton sales summarized by state (county level information available upon request) except for the ten restricted counties in Texas; in those counties, Monsanto must provide county-level sales information.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

A stamped copy of the label is enclosed for your record

Sincerely,

A handwritten signature in cursive script, appearing to read "Janet Andersen", written in black ink.

Janet Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division (7511P)

Bollgard II[®] Cotton

Bacillus thuringiensis subsp. *kurstaki*
Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production
[PV-GHBK11] in event MON 15985 cotton0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production
[PV-GHBK04] in event MON 15985 cotton0.00004 - 0.00052%*

Other Ingredients:

Substance produced by the marker genes and the genetic material necessary for their production
[PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton.....0.0022-0.0304%*

*Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

[®] Bollgard II is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

ACCEPTED
with COMMENTS
In EPA Letter Dated
JUN 01 2007
Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
524-522

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (B.t.k.) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the above listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins is planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production, and insect-resistance management.
4. Bollgard II must not be planted nor sold for commercial planting in Hawaii, Puerto Rico, U.S. Virgin Islands, south of Route 60 (near Tampa) in Florida, and in the following counties in the Texas panhandle: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of Bollgard II cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton.

**A Plan for Monitoring and Mitigating Resistance to Bollgard II®
Cotton in Heliothine Pests
November 12, 2004**

I. RATIONALE

Bollgard II® cotton is an important pest management tool for U.S. cotton farmers. Since the Bollgard® cotton introduction in 1996, this technology has provided economical and effective control of two key heliothine pests, the tobacco budworm (TBW), *Heliothis virescens*, and the cotton bollworm (CBW), *Helicoverpa zea*. The deployment of Bollgard cotton has ended the cotton farmers' near total reliance on chemical insecticides for the management of heliothine insects. However, the evolution of resistance in heliothine pests to the Cry1Ac protein expressed in Bollgard cotton cultivars is a potential threat to the sustainability of Bollgard cotton. Bollgard II cotton was developed as a two-gene product expressing both Cry1Ac and Cry2Ab2 proteins in an attempt to mitigate potential resistance evolution. As a condition of registration of Bollgard II cotton (EPA Reg. No. 524-522), the U.S. EPA required Monsanto Company to develop and implement a program to monitor for insect resistance to the Cry1Ac protein expressed in both Bollgard cotton and Bollgard II cotton as well as the Cry2Ab2 protein expressed only in Bollgard II cotton, and direct mitigation actions against resistance if it were to occur to the Bollgard II cotton product. This document describes a Remedial Action Plan for Bollgard II cotton.

II. COMPONENTS AND ORGANIZATION

The registrant is responsible for organizing, deploying, and financially supporting the Bollgard II cotton resistance monitoring and mitigation program for TBW and CBW.

Agricultural consultants, state and federal entomologists, growers, dealers' field personnel, and others will be enlisted, as volunteers and contractors, to assist in surveying, detection, verification, and other components of the monitoring program. To the extent possible, the registrant will educate and encourage persons working in cotton pest management to be conscious of and alert to resistance evolution events. When appropriate, the registrant will hire qualified individuals to execute specific protocols for resistance monitoring, such as for the testing of suspected resistant insects, and enlist necessary expertise, assistance, supplies, etc., for the conduct of a successful program.

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III. MONITORING APPROACHES

Monitoring provides the capability of detecting the presence of rare resistance alleles in field populations, even though product failure may not be occurring. If the monitoring programs demonstrate the presence of field resistance in a population, then steps will be taken to characterize the resistance.

A. Susceptibility Monitoring

Monitoring for resistance evolution to Bollgard II cotton in TBW and CBW will also include the ongoing USDA/ARS project at Stoneville, MS. The goal of this program is to detect early changes in the frequency of Cry1Ac and/or Cry2Ab resistance alleles in TBW and CBW. Data from the program may have early detection benefits and may provide direction for the in-field monitoring activity.

Monsanto also will continue to work with academic experts to evaluate the suitability of alternative monitoring and screening methods as discoveries are made on the nature of Cry1Ac and Cry2Ab2 insect resistance.

B. Integrated Pest Management (IPM)-Based Monitoring

Monitoring for the early detection of resistance to Bollgard II cotton poses several significant challenges. The program will require insect sampling each season when TBW and CBW are infesting cotton and must be conducted across most of the U.S. cotton belt. One reasonable and cost effective approach is IPM-based monitoring. A majority of cotton fields in the U.S. are normally scouted for heliothine pest insects on an annual basis. IPM consultants (and their employed scouts), cotton growers, and/or commercial agricultural dealers selling crop services and products routinely monitor insect pests on a weekly or more frequent basis each season. The IPM-based monitoring strategy integrates resistance monitoring with regular cotton scouting, other pest management observations, and those also conducted on Bollgard cotton for TBW and CBW. The approach potentially taps the efforts of hundreds of pest management consultants and commercial representatives and thousands of cotton scouts.

IPM consultants, growers and/or commercial representatives will be requested to notify the registrant of unusual TBW and/or CBW survival in Bollgard II cotton. The registrant will work with IPM consultants, growers, and commercial representatives and communicate the need to implement IPM-based monitoring for resistance. The communication may include seminars, brochures, videos, presentations, and other effective techniques. The IPM-based monitoring will be effectively marketed and may include promotions and other forms of encouragement. A toll-free number and other opportunities will be used to facilitate communication between the field team conducting the monitoring and the registrant. The registrant will support this program with the supplies needed (e.g., protocol, insect collection instructions, supplies, etc.).

TBW and/or CBW larvae with unusual survival will be collected from Bollgard II cotton fields and held on non-B.t. plant tissue or placed on appropriate diet for identification and testing purposes. The registrant will coordinate this effort with state and ARS entomologists to provide directions for collecting/holding larvae and to make insect diet available in a timely manner.

IV. DEFINITIONS

A. Resistance Event, Putative—One or more of the following will define a putative resistance event after confirmation of the plant genotype:

1. Susceptibility Monitoring:

Significantly elevated survival of TBW and/or CBW larvae in a standardized laboratory diagnostic dose assay at the 95% confidence level compared to baseline data for susceptible populations.

2. IPM-Based Monitoring:

- a. Survival of TBW to second or later instar with at least two larvae per 100 flowers, squares, and bolls (proportional to the plants fruiting profile) with: 1] normal Cry1Ac and Cry2Ab2 protein titer in Bollgard II cotton plants, and 2] Bollgard II cotton plant populations of $\geq 98\%$ purity, plus verification of statistically significant survival at the 95% confidence level as compared to appropriate baseline data for TBW.
- b. Survival of CBW to third or greater instar with ≥ 15 larvae per 100 flowers, squares, and bolls (proportional to the plants fruiting profile) with: 1] confirmation that the CBW infestation was typical (an abnormally high CBW infestation may necessitate a higher threshold), 2] normal Cry1Ac and Cry2Ab2 protein titer in Bollgard II cotton plants, and 3] a Bollgard II cotton plant population of $\geq 98\%$ purity, plus verification of statistically significant survival at the 95% confidence level as compared to appropriate baseline data for CBW.

B. Resistance Event, Confirmation

Resistance to Bollgard II cotton will be confirmed by verification of statistically significant survival at the 95% confidence level as compared to appropriate baseline data. Confirmation of results in the same testing laboratory or another laboratory can be considered as appropriate. Baseline ranges of Cry1Ac LC₅₀ values for control of TBW and/or CBW have been reported in the literature (Stone and Sims, 1993; Luttrell et al., 1999) and Cry2Ab2 LC₅₀ values for control of TBW and/or CBW are currently being established from 2002 and 2003 data.

V. MITIGATION ACTIONS

A. *Resistance Event, Putative*

Surveys, plant tissue collections, and/or in-field analysis will be conducted as needed to determine the genotype purity of the plant population and expressed titer of Cry1Ac and Cry2Ab2 in infested Bollgard II cotton plants.

The registrant will notify the appropriate state CES entomologist(s) working with cotton after confirmation of plant genotype and request his/her cooperation to further clarify the putative resistance event. Fields within the vicinity of a putative resistance field(s) (e.g., within 1 mile) will be thoroughly sampled for further evidence of resistance. If substantiating data are gathered, the sampling will be expanded to obtain a preliminary estimate of the extent of increased TBW and/or CBW survival. To this end, interviews with consultants, extension agents, and growers will be conducted.

Collections of TBW and/or CBW will be made for establishment of laboratory colonies. Moths and larvae will be collected from the infested field(s) and from other Bollgard II cotton fields identified in the survey. Progeny from the colony(s) will be subjected to standard bioassay testing.

After confirmation of the Bollgard II cotton genotype in the affected field, and depending on the timing, the extent and the nature of the resistance, the registrant may instruct growers to use alternative control measures to control the pest suspected of resistance in the Bollgard II cotton region with the detection. In addition, the registrant may also instruct growers to destroy crop residues in the affected region (i.e., within one month) with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's pest population.

B. *Resistance Event, Confirmed*

The registrant assumes responsibility for the implementation of resistance mitigation actions undertaken in response to the occurrence of resistance during the growing season. In cases of *confirmed* resistance, the following strategy for Bollgard II cotton varieties will be implemented:

The registrant will report all instances of confirmed pest resistance, as defined above, to the Agency within 30 days. Upon identification of a confirmed instance of resistance, registrants will take the following mitigation measures immediately:

1. Notify customers and extension agents in the affected area;

2. Instruct that customers and extension agents in the affected area use additional control measures to reduce or control the local target pest population;
3. If circumstances deem it appropriate (the pest, the extent of resistance, the timing of the resistance and the nature of the resistance), require that customers and extension agents in the affected area incorporate crop residues into the soil following harvest, to minimize the possibility of over-wintering insects; and
4. If circumstances deem it appropriate (the pest, the extent of resistance, the timing of the resistance and the nature of the resistance), stop sale and distribution of Bollgard II cotton immediately in the remedial action zone (may be a single county or multiple counties) where the resistance has been shown until an effective local mitigation plan approved by EPA has been implemented.

Within 90 days of a confirmed instance of pest resistance, as defined above, the registrant will:

1. Notify the Agency of the immediate mitigation measures that were implemented;
2. Submit to the Agency a proposed long-term resistance management action plan for the affected area;
3. Work closely with the Agency in ensuring that an appropriate long-term resistance management action plan for the affected area is implemented;
4. Implement an action plan that is approved by EPA, consisting of some or all of the following elements as appropriate:
 - a. Inform customers and extension agents in the affected area of pest resistance;
 - b. Increase monitoring in the affected area and ensure that local target pest populations are sampled on an annual basis;
 - c. Recommend additional measures to reduce or control target pest populations in the affected area;
 - d. Implement intensified local IRM measures in the affected area based on the latest research results; and
 - e. Coordinate the implementation of the remedial action strategy by the Agency with other stakeholders.

For mitigation of resistance in the growing season(s) following the confirmed resistance incident(s), the registrant will recommend appropriate measures based upon considering

the pest, the extent of the resistance, and the nature of the resistance identified. The registrant will recommend use of some or all of the following procedures:

1. Notification of all relevant personnel (e.g., growers, consultants, extension agents, seed distributors, processors, university cooperators, and state/federal authorities) in the affected region of the resistance situation;
2. Intensified monitoring and surveillance in the affected region(s) and definition of the boundaries of the affected region. These studies could also include assays to determine the potential for cross-resistance in the resistant population;
3. The development and use of alternative resistance management strategies for controlling the resistant pest(s) on cotton in the affected region;
4. Where sales have been suspended, maintenance of the suspension of all Bollgard II cotton products and similar products with one or more of the same B.t. proteins in the affected region, which would remain in place until susceptibility has been determined to have returned to acceptable levels; and
5. If EPA agrees that an effective local resistance management plan has been implemented which mitigates resistance, the registrant can resume sales in the affected county or counties.

VI. REFERENCES

- Luttrell, R. G., L. Wan, and K. Knighten. 1999. Variation in susceptibility of Noctuid (Lepidoptera) larvae attacking cotton and soybean to purified endotoxin proteins and commercial formulations of *Bacillus thuringiensis*. J. Econ. Entomol. 92:21-32.
- Stone, T. B. & S. R. Sims. 1993. Geographic susceptibility of *Heliothis virescens* and *Helicoverpa zea* (Lepidoptera: Noctuidae) to *Bacillus thuringiensis*. J. Econ. Entomol. 86:989-994.

Cooperative Extension

T. J. Dennehy
Extension Arthropod Resistance
Management Laboratory
Department of Entomology
University of Arizona

--Reviewed 3 June, 2002, by the AZ Bt Cotton Working Group--

A Remedial Action Plan for Responding to Pink Bollworm Resistance to Bt Cotton in Arizona

*Formulated by the Arizona Bt Cotton Working Group
T.J. Dennehy, Chair*

I. Definitions

Definition #1. Putative Resistance Event--A Cautionary Alert

A putative resistance event consists of any field of Bt cotton in which collections of 100 bolls yield $\geq 3\%$ large larvae (≥ 3 rd instar), pupae or PBW exit holes in bolls. This is a cautionary alert and must not be construed to be a verified resistance event until: 1) the plants from which collections were made are confirmed to produce Bt toxin and, 2) bioassays are completed that confirm the reduced susceptibility of the pink bollworm surviving on Bt cotton.

Definition #2. A Verified Resistance Event.

A putative resistance event becomes verified if three conditions are met:

- 1) A sample of 1000 bolls yields $\geq 3\%$ containing large larvae (≥ 3 rd instar), pupae, or PBW exit holes.
- 2) An ELISA test for Bt toxin yields a positive response for Bt toxin in a sample of 25 young bolls collected from plants on which PBW larvae were found in the cotton field of interest.
- 3) Standardized laboratory bioassays demonstrate that the PBW population of interest is significantly less susceptible to CryIA(c) toxin than were baseline populations in 1997 (Simmons et al. 1998 and unpublished).

II. Remedial Action

1) Putative Resistance Event: Year of First Detection.

Within one week of confirming that a Bt field has $\geq 3\%$ of bolls containing large larvae (≥ 3 rd instar), pupae, or PBW exit holes, alternative PBW controls should be implemented in that field. Measures should include one or more of the following:

- Adulticide treatments if crop is in active growing state, followed by additional insecticide applications (2) on a 3-day schedule, or based on adult emergence as predicted by phenological models.

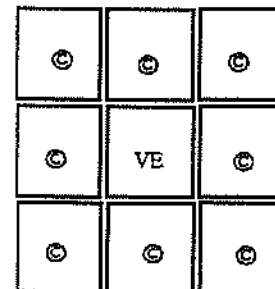
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- If crop is senescent, consider chemical termination to reduce squares and bolls less than 10 days old, accelerate harvest, and destroy crop residue by shredding of stalks followed by disking, and deep plowing (6" burial).
- If crop is defoliated, accelerate harvest and destruction of crop residue to further limit survival of resistant pink bollworm. Destroy crop residue as indicated above.

2) Verified Resistance Event: Year of First Detection.

- A. If resistance is verified in time to permit it, we strongly recommend that measures be taken to reduce the numbers of resistant pink bollworm that survive to the next season. These could include: adulticide treatments, early termination, and early plowdown, consisting of shredding of stalks followed by disking, and deep plowing (6" burial). Winter irrigation is also recommended to reduce survivorship of overwintering larvae.

- B. Bt fields in the immediate vicinity of a verified resistance event should be examined to detect unusual survivorship of PBW. Results should be used to delimit the size of the affected area and to define the 'Bt remedial action zone.' We suggest sampling 300 bolls from all Bt fields located within the 8 sections of land (designated by © in the adjacent figure) that surround the section of land on which the verified event (VE) occurred. Bt cotton fields containing $\geq 3\%$ bolls infested with PBW should be considered affected by resistance for the purpose of delimiting the remedial action zone.



- C. The 'Bt remedial action zone' should be delineated using GPS mapping technology currently in use at the ACRPC. This will ensure accurate records of locations of verified resistance. The remedial action zone should include all sections of land falling within 6 miles of the perimeter of the section(s) of land in which verified resistance events occurred (see figure below).
- D. At such time as fields with verified resistance are detected in >3 different townships within a particular cotton growing region, the entire region may be designated as a Bt resistance remedial action zone.

3) Verified Resistance Event: Next Year's Actions.

- A. If verified resistance occurred in only Bollgard, then only Bollgard II, or non-Bt cotton should be planted in the remedial action zone in the year(s) immediately following verification of resistance. If verified resistance occurred in Bollgard and/or Bollgard II, then only non-Bt cotton should be planted in the remedial action zone in the year(s) immediately following verification of resistance. These measures should be maintained until such time as bioassays of PBW from the remedial action zone demonstrate that the frequency of resistant individuals has declined to acceptable levels. What will constitute levels of resistance acceptable for allowing resumption of use of Bt cotton will be determined on an *ad hoc* basis by our Working Group, based on research experience that members have obtained from studies of pink bollworm resistance to CryIAC.

The ecological fitness of PBW resistant to CryIAC is not known at this time and the dynamics of resistance in the field will likely be influenced by factors including overwintering survival of resistant

larvae, intensity of resistance to Cry1Ac, and growth and survival of resistant PBW on Bt and non-Bt plants. Therefore, new information derived from field and laboratory studies currently underway will be pivotal for determining the frequency of resistance (to Cry1Ac or to mixtures of Cry1Ac and Cry2Ab2) at which use of Bt cotton could reasonably be resumed within an area previously designated as a Bt remedial action zone.

- B. It is assumed that published University recommendations for monitoring and chemical control of pink bollworm will be followed within remedial action zones in order to limit survival of resistant pink bollworm. Additionally, timely crop termination (no top-crop) and early and thorough crop destruction, as detailed above, is strongly encouraged. Releases of sterile pink bollworm should also be considered.
- C. The recommendations of our working group regarding 1) Bt refuge management and 2) remedial action for responding to PBW resistance in Arizona should be re-evaluated annually and modified to account for new findings. Educational programs and regulatory measures should be devised to promote a high level of producer compliance with recommendations.

III. Organizational Roles

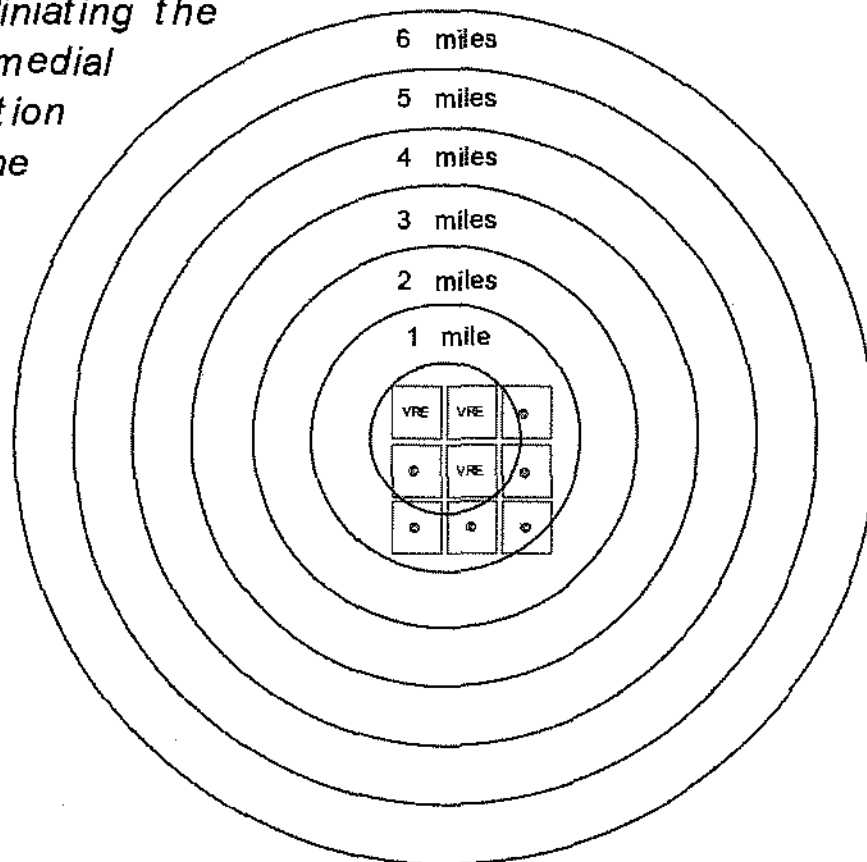
- 1) The Arizona Department of Agriculture should serve a central role in implementing this plan, compiling statistics on use of Bt cotton, and promoting compliance with remedial action.
- 2) Consideration should be given on a case-by-case basis for making funds available to compensate producers for costs associated with implementing the remedial action measures recommended herein.
- 3) A sampling team comprising personnel from relevant organizations (ACRPC, UA, USDA) will be formed. This team will be ready in August of every year to conduct the sampling required to delineate resistance problems (as detailed above). Similarly, facilities and personnel at EARML will be prepared to conduct bioassays or molecular tests of up to 40 different populations of PBW per season. Funding for these efforts must be sustained.
- 4) Monsanto should agree to suspend Bt cotton sales in remedial action zones until such time as either the frequency of resistant individuals is shown to have declined to levels deemed acceptable by our Working Group, or new Bt products free of cross-resistance are introduced, and the Arizona Bt Cotton Working Group has concluded that a modified resistance management strategy has been adopted that will adequately reduce the rate of development of further resistance to Bt cotton products.

References

- a. Simmonns, A.L., T.J. Dennehy, B.E. Tabashnik, L. Antilla, A. Bartlett, D. Gouge and R. Staten. 1998. Evaluation of B.t. cotton deployment strategies and efficacy against pink bollworm in Arizona. Proc. 1998 Beltwide Cotton Conferences. 1025-1030.
- b. Liu, Y.-B., Tabashnik, B.E., Dennehy, T.J., Patin, A.L., and Bartlett, A.C. 1999. Development time and resistance to Bt crops. Nature 400:519.
- c. Patin, A.L., Dennehy, T.J., Sims, M.A., Tabashnik, B.E., Liu, Y.B., Antilla, L., Gouge, D., Henneberry, T.J., and R. Staten. 1999. Status of pink bollworm susceptibility to Bt in Arizona. Proc. Beltwide Cotton Conferences. National Cotton Council. Pp. 991-996.

- d. Tabashnik, B.E., A.L. Patin, T.J. Dennehy, Y.-B. Liu, E. Miller and R.T. Staten. 1999. Dispersal of pink bollworm (*Lepidoptera Gestechnidae*) males in transgenic cotton that producer a *Bacillus thuringiensis* toxin. *J. Econ. Entomol.* 92:772-780.

*Deliniating the
Remedial
Action
Zone*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Biopesticides and Pollution
Prevention Division (7511P)
Ariel Rios Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

EPA Reg. Number:

524-522

Date of Issuance:

6/1/07

NOTICE OF PESTICIDE:

x Registration
Reregistration
(under FIFRA, as amended)

Term of Issuance: Unconditional

Name of Pesticide Product: Bollgard II Cotton

Name and Address of Registrant (include ZIP Code):

Monsanto Company
800 North Lindbergh Blvd
St. Louis, MO 63167

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Submit/cite all data required for registration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. The following information regarding commercial production must be included in the grower guide for Bollgard II® cotton and is a term of this registration:
 - a) No planting or sale for commercial planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
 - b) No planting or sale for commercial planting of Bollgard II cotton is permitted in Hawaii, Puerto Rico, and the U.S. Virgin Islands.
 - c) No planting or sale for commercial planting of Bollgard II cotton is permitted in the following counties in the Texas panhandle: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

Signature of Approving Official:

G. J. [Signature]

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Date:

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DATE	5/31/07	6/1/07						

3. The following information regarding test plots and seed production must occur on bags of Bollgard II cotton intended for these purposes and is a term of this registration:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

4. Insect Resistance Management Program Elements. The required IRM program for Bollgard II cotton must have the following elements:

- a. Requirements for a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- b. Requirements for Monsanto to prepare and require Bollgard II cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the IRM requirements;
- c. Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- d. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- e. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1Ac and Cry2Ab2 proteins in the target insects;

f. Requirements for Monsanto to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

g. Requirements for annual reports on or before January 31st each year for compliance assurance (including grower education) and sales. The tobacco budworm and cotton bollworm annual resistance monitoring reports must be submitted to EPA on or before June 30th each year and for pink bollworm, the annual resistance monitoring report must be submitted to EPA on or before December 31st each year. See Annual Reports section below.

5. Insect Resistance Management Requirements

- a. **Refuge Requirements for Pink Bollworm Resistance Management only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.**

All growers of Bollgard II® cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of Bollgard II® cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed

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SYMBOL	Bollgard II cotton. The non- <i>Bt</i> cotton may be treated with sterile insects, insecticides (excluding foliar <i>Bt</i> products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non- <i>Bt</i>
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cotton refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard II cotton.

b. Natural Refuge Requirements for Tobacco Budworm and Cotton Bollworm Resistance Management only in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas (excluding the following counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler), and Virginia.

1) Tobacco budworm sampling must be conducted for at least one year in west Texas, Alabama, and Tennessee. An appropriate gossypol analysis, statistical analysis, calculation of effective and natural refuge, and simulation modeling must be performed to determine the likelihood of tobacco budworm resistance to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II® cotton using natural refuge. Previously, these states had only a single year of sampling data and analysis to support the natural refuge. The new data collected in 2007 and/or 2008 must be compared with previously collected data (2004 to 2006, depending on the location) to confirm the effectiveness of a natural refuge.

A report of these findings must be submitted to EPA on or before January 31st following the year of collection.

2) Monsanto must submit data to EPA by January 31st, 2012, and every five years thereafter, to support an EPA reassessment of the natural refuge and to confirm its effectiveness with tobacco budworm and cotton bollworm. The data must include: resistance monitoring data, cropping pattern analysis, and simulation modeling to reexamine levels of effective refuge in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Both cropping and land use patterns can change over time, which could impact the amount of natural refuge available to tobacco budworm and cotton bollworm relative to cotton. If based on this reassessment, EPA determines that additional tobacco budworm and/or cotton bollworm sampling, gossypol analysis, statistical analysis, and simulation modeling are needed to justify continuation of the natural refuge, Monsanto must submit these data within the EPA requested timeframe. If EPA's assessment concludes that the natural refuge is no longer scientifically supported, Monsanto has agreed and must submit an application to amend the registration to restore the structured refuge requirements previously required for tobacco budworm and cotton bollworm uses.

- 3) It is recommended that Monsanto develop a more complex, spatial model of resistance for Bollgard II cotton that further considers the evolution of resistance "hotspots" (i.e. localized areas of resistance) and provide EPA with this information. Key issues like spatial structure, linkage disequilibrium, and differential movement of males and females have not yet been explored in detail for pyramided Bt proteins. Such models would be more desirable to examine the resistance evolution at the local level where natural refuge may be limited for one or more generations of tobacco budworm.

c. Grower Agreements

While Monsanto will have flexibility to design its program to fit its own business practices, the registration is specifically conditioned on meeting the following requirements.

- 1) Persons purchasing the Bollgard II cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
- 3) Monsanto must continue to implement an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
- 4) Monsanto must continue to use an approved grower agreement. If Monsanto wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this registration.
- 5) Monsanto must continue an approved system which is reasonably likely to assure that persons purchasing the Bollgard II cotton sign grower agreement(s).
- 6) Monsanto shall maintain records of all Bollgard II cotton grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7) Beginning January 31, 2008 and annually thereafter, Monsanto shall

SYMBOL	provide EPA with a report on the number of units of the Bollgard II cotton seed shipped and not returned and the number of such units that were sold to persons
SURNAME	who have signed grower agreements. The report shall cover the time frame of the
DATE	twelve-month period covering the prior October through September.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

d. IRM Education and IRM Compliance Monitoring Programs

Monsanto must implement the following IRM education and compliance monitoring programs:

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bollgard II cotton users the importance of complying with the IRM program. The program shall include information encouraging Bollgard II cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bollgard II cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each Bollgard II® cotton grower separate from the grower agreement. Monsanto shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Annually, Monsanto shall provide a report to EPA any substantive changes to the grower education activities as a part of the overall IRM compliance assurance program report.

4) Monsanto shall continue to implement an ongoing, approved IRM compliance assurance program in the states of Arizona, California, and New Mexico and in the following Texas Counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. The program is designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Bollgard II® cotton product. Other required features of the program are described in paragraphs 5 - 12 below.

5) Monsanto shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bollgard II cotton for an

individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bollgard II cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year. Monsanto shall confer with EPA on the design and content of the survey prior to its implementation.

7) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto will confer with the Agency prior to adopting any changes.

8) Monsanto must conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with Bollgard II® cotton growers to perform assessments of compliance with IRM requirements. There is no minimum cotton acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

9) Monsanto shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

10) If a grower, who purchases Bollgard II cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

11) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto, the number of tips investigated, the percent of growers who were not complying with the IRM requirements, and the follow-up actions taken...

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12) Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

e. Insect Resistance Monitoring.

Monsanto must conduct an annual resistance monitoring program for *Heliothis virescens* (tobacco budworm) *Helicoverpa zea* (cotton bollworm), and *Gossypiella pectinophora* (pink bollworm) for the Cry1Ac and Cry2Ab2 toxins expressed in Bollgard II cotton as early as possible. Resistance monitoring programs must include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following terms and conditions:

- 1) Monsanto must submit a revised Bollgard II cotton (Cry2Ab2 and Cry1Ac toxins) resistance monitoring plan for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm) to EPA by September 1, 2007. A revised resistance monitoring plan approved by EPA must be used beginning in the 2008 growing season. The monitoring program must include increased sampling for tobacco budworm and cotton bollworm in the areas that have the greatest variability and potentially lowest levels of effective natural refuge. Sampling efforts should include all of the "worst-case" counties identified in Monsanto's 2004 to 2006 analyses of natural refuge in the states of Texas, Tennessee, Mississippi, Louisiana, Arkansas, Alabama, Georgia, and North Carolina. BPPD believes that resistance monitoring for tobacco budworm and cotton bollworm resistance to Cry1Ac and Cry2Ab2 will have added importance with adoption of a natural refuge as a resistance management strategy.
- 2) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest.
- 3) The following testing scheme for survivors of the diagnostic or discriminating concentrations (or identified survivors of any resistance detection method) must be implemented: 1) Determine if the observed effect is heritable; 2) Determine if the increased tolerance can be observed in the field (i.e., survive on Bollgard II® cotton plants); 3) Determine if the effect is due to resistance, 4) Determine the nature of resistance (dominant, recessive), 5) Determine the resistance allele frequency, 6) Determine, in subsequent years, whether the resistance allele frequency is increasing, and 7) Determine the geographic extent of the resistance allele (or alleles) distribution. Should the resistance allele frequency be increasing and spreading, a specific remedial action plan should be designed to mitigate the extent of Bt resistance. See section f. ("Remedial Action Plans") below.

- 4) Monsanto must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, cotton leafperforator and European corn borer. Monsanto will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto will investigate all damage reports. See Remedial Action Plans section below.
- 5) Monsanto must provide to EPA for review and approval any revisions to the tobacco budworm, cotton bollworm, and pink bollworm resistance monitoring plans prior to their implementation.
- 6) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

f. Remedial Action Plans

Specific remedial action plans are required for Bollgard II® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial (Mitigation) Action Plan for Tobacco Budworm and Cotton Bollworm (Attachment I)

If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto must implement the Remedial Action Plan approved by EPA. Monsanto must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

2) Remedial Action Plan for Pink Bollworm (Attachment II)

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto must implement the Arizona Bt Cotton Working Group's Remedial Action Plan.

Monsanto must obtain approval from EPA before modifying the Arizona Bt Cotton Working Group's Remedial Action Strategy.

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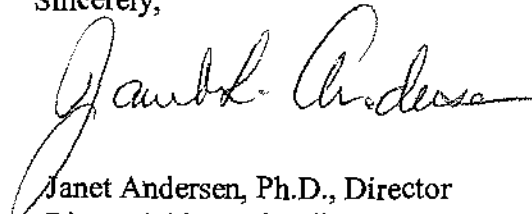
g. Annual Reports for Sales, Grower Education, Compliance Assurance, Grower Agreements, and Resistance Monitoring.

Annually by January 31st, Monsanto will provide EPA a report that contains the following information: number of units of the Bollgard II® cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements, results of the compliance assurance program including any substantive changes to the grower education program, and a sales report. The annual sales report should contain a summary of all Bollgard II cotton sales summarized by state (county level information available upon request) except for the ten restricted counties in Texas; in those counties, Monsanto must provide county-level sales information.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

A stamped copy of the label is enclosed for your record

Sincerely,

A handwritten signature in cursive script, appearing to read "Janet Andersen".

Janet Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division (7511P)



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 (202) 383-2866	EPA Registration Number / File Symbol: Reg. No. 524-522
Active Ingredient(s) and/or representative test compound(s): <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in cotton	Date: May 30, 2007
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: Bollgard II cotton

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies set offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ [Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

☒ I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature 	Date May 30, 2007	Typed or Printed Name and Title Melinda C. McCann, Regulatory Affairs Manager
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Date: May 30, 2007

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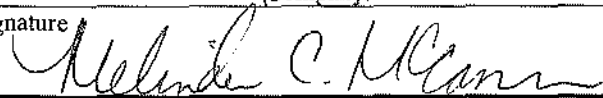
Page 1 of 26

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2100	Sammons, D. (1994) <i>B.t.t.</i> HD-73 Protein Dose Formulation and Determination of Dose for an Acute Mouse Feeding Study. MSL-13169. Unpublished study prepared by Monsanto Company.	43145212	Monsanto Company	OWN	Submitted 16-Feb-1994
885.3050	Naylor, M. (1993) Acute Oral Toxicity of <i>Bacillus thuringiensis</i> var. <i>kurstaki</i> (Cry1Ac) HD-73 Protein in Albino Mice. MSL-12708. Unpublished study prepared by Monsanto Company.	43145213	Monsanto Company	OWN	Submitted 16-Feb-1994
885.1400 885.1500 885.2400 885.2500	Kolwyck, D; Hamilton, K; Reed, A. (1999) GUS Protein Levels in Insect Protected Cotton Samples Produced in the U.S. Field Trials. MSL-16097. Unpublished study prepared by Monsanto Company.	44939402	Monsanto Company	OWN	Submitted 30-Sep-1999
885.1100 885.2100	Holleschak, G.; Thoma, R.; Lee, T.C.; Hileman, R.E.; Astwood, J.D. (1999) Assessment of the Equivalence of Proteins Expressed in Cotton Events 15813 and 15985. MSL-16093. Unpublished study prepared by Monsanto Company.	44939403	Monsanto Company	OWN	Submitted 30-Sep-1999
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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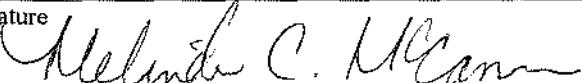
Page 2 of 26

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2100	Harrison, L.A.; Biest, N.A.; Leimgruber, R.; Padgett, S.R. (1996) Preparation, Characterization, and Confirmation of Does for an Acute Mouse Feeding Study with β -D-Glucuronidase. MSL-12979. Unpublished study prepared by Monsanto Company.	44939404	Monsanto Company	OWN	Submitted 30-Sep-1999
885.2100 885.1300	Gustafson, K.S.; Hileman, R.E.; Astwood, J.D. (1999) Bioinformatics Analysis of GUS Protein Sequence Utilizing an Allergen Database. MSL-16263. Unpublished study prepared by Monsanto Company.	44939405	Monsanto Company	OWN	Submitted 30-Sep-1999
885.2100 885.1300	Hileman, R.E.; Gustafson, K.S.; Astwood, J.D. (1999) Bioinformatics Analysis GUS Protein Sequence Utilizing Toxin and Public Domain Genetic Databases. MSL-16264. Unpublished study prepared by Monsanto Company.	44939406	Monsanto Company	OWN	Submitted 30-Sep-1999
885.2100	Ream, J. (1996) Assessment of the <i>In vitro</i> Digestive Fate of β -Glucuronidase. MSL-14607. Unpublished study prepared by Monsanto Company.	44939407	Monsanto Company	OWN	Submitted 30-Sep-1999
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DATA MATRIX

Date: May 30, 2007
EPA Reg No./File Symbol: 524-522 Page 3 of 26
Applicant's/Registrant's Name & Address:
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167
Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1400 885.1500 885.2400 885.2500	Kolwyck, D; K Hamilton; and A Reed. (1999) Protein Levels in Insect Protected Cotton Samples Produced in the 1998 U.S. Field Trials. MSL-16612. Unpublished study prepared by Monsanto Company.	44966601	Monsanto Company	OWN	Submitted 5-Nov-1999
885.3050	Bechtel, C.L. (1999) Acute Oral Toxicity Study of Insect Protection Protein 2 (IPP2) in Mice. MSL-16381. Unpublished study prepared by Monsanto Company.	44966602	Monsanto Company	OWN	Submitted 5-Nov-1999
885.2100	Leach, J.N.; Hileman, R.E.; Martin, J.W.; Nemeth, M.A.; Astwood, J.D. (1999) Assessment of the <i>in vitro</i> Digestibility of Insect Protection Protein 2 (IPP2) Utilizing Mammalian Digestive Fate Models. MSL-16046. Unpublished study prepared by Monsanto Company.	44966603	Monsanto Company	OWN	Submitted 5-Nov-1999
885.2100 885.1300	Hileman, R.E.; Astwood, J.D. (1999) Bioinformatics Analysis of Insect Protection Protein 2 (IPP2) Sequence Utilizing an Allergen Database. MSL-16094. Unpublished study prepared by Monsanto Company.	44966604	Monsanto Company	OWN	Submitted 5-Nov-1999

Signature

Name and Title
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Regulatory Affairs Mgr.

Date
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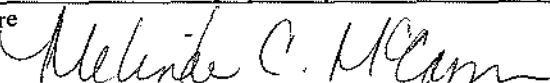
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Date: May 30, 2007			EPA Reg No./File Symbol: 524-522		Page 4 of 26
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167			Product: Bollgard II cotton		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.2100 885.1300	Hileman, R.E.; Astwood, J.D. (1999) Bioinformatics Analysis of Insect Protection Protein 2 (IPP2) sequence Utilizing Toxin and Public Domain Genetic Databases. MSL-16095. Unpublished study prepared by Monsanto Company.	44966605	Monsanto Company	OWN	Submitted 5-Nov-1999
885.3050	Naylor, M.W. (1992) Acute Oral Toxicity Study of β -D-Glucuronidase (GUS) Protein in Albino Mice. MSL-12485. Unpublished study prepared by Monsanto Company.	44988801	Monsanto Company	OWN	Submitted 30-Sep-1999
885.1100 885.2100	Hileman, R.E.; Pyla, P.D.; Lee, T.C.; Astwood, J.D. (1999) Characterization of Insect Protection Protein 2 (IPP2) Produced by Fermentation. MSL-15742. Unpublished study prepared by Monsanto Company.	44999301	Monsanto Company	OWN	Submitted 5-Nov-1999
885.1100 885.1200 885.1300 885.2100	Doherty, S.; Hamilton, K.A.; Lirette, R.P.; Borovkova, I. (2000) Amended Report for Molecular Characterization of Cotton Event 15985. MSL-16620. Unpublished study prepared by Monsanto Company.	45086303	Monsanto Company	OWN	Submitted 4-Apr-2000
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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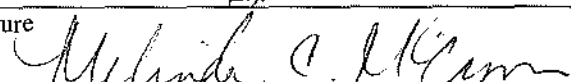
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V. (2000). Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Honey Bee Larvae. MSL-16175, CA-99-059, and CAR 157-99. Unpublished study prepared by California Agricultural Research.	45086307	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4380	Maggi, V. (2000) Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (<i>Apis mellifera</i> L.). 99-858E, CA-99-058, and CAR 156-99. Unpublished study prepared by California Agricultural Research.	45086308	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). MSL-16171 and WL-99-061. Unpublished study prepared by Wildlife International Ltd.	45086309	Monsanto Company	OWN	Submitted 4-Apr-2000
885.1100 885.1200 885.1500	Monsanto Company. (2000) Administrative Materials in Support of the Request for the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Corn (<i>Zea mays</i> L.) and Cotton (<i>Gossypium hirsutum</i> L.).	45086300	Monsanto Company	OWN	Submitted 4-Apr-2000
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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DATA MATRIX

Date: May 30, 2007

EPA Reg No./File Symbol: 524-522


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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Hamilton, K.; Reed, A. (1999) Field Report: Production of Tissue Samples from Insect Protected Cotton Events Grown in the 1998 U.S. Field Season. MSL-16019. Unpublished study prepared by Monsanto Company.	45086301	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-16173 and WL-99-062. Unpublished study prepared by Wildlife International Ltd.	45086310	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16172 and WL-99-060. Unpublished study prepared by Wildlife International Ltd.	45086311	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. 99-858E, 139-445, and WL-99-067. Unpublished study prepared by Wildlife International Ltd.	45086313	Monsanto Company	OWN	Submitted 4-Apr-2000
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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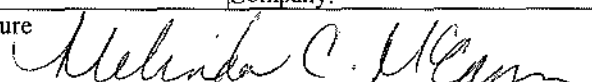
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Teixiera, D. (2000) Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (<i>Folsomia candida</i>): Amended Final Report. MSL-16174 and SB-99-063. Unpublished study prepared by Springborn Laboratories, Inc.	45086314	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4050	Gallagher, S.; Grimes, J.; Beavers, J. (2000) Insect Protection Protein 2 In Cottonseed Meal: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16178. Unpublished study prepared by Wildlife International, Ltd.	45086316	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4200	Li, M.; Robinson, E. (2000) Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish. MSL-16179. Unpublished study prepared by Thad Cochran National Warmwater Aquaculture Center.	45086318	Monsanto Company	OWN	Submitted 4-Apr-2000
885.5200	Dubelman, S.; Martin, J.; Bhalgat, M. (2001) Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Insect Protein 2 in Cotton Leaf Tissue. MSL-16185. Unpublished study prepared by PTRL East, Inc. and Monsanto Company.	45337101	Monsanto Company	OWN	Submitted 21-Feb-2001
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	



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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4380	Maggi, V. (2000) Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein on Honey Bee Larvae. MSL-16961. Unpublished study prepared by California Agricultural Research, Inc.	45337102	Monsanto Company	OWN	Submitted 21-Feb-2001
885.4200	Li, M.; Robinson, E. (2001) Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish. Amended MSL-16179. Unpublished study prepared by Thad Cochran National Warmwater Aquaculture Center.	45337103	Monsanto Company	OWN	Submitted 21-Feb-2001
885.1100 885.1200 885.1300 885.2100	Doherty, S.; Lirette, R.; Hamilton, K. (2000) Molecular Analysis of the Stability of Cotton Event 15985. MSL-16749. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 21-Feb-2001
885.2300	D. Kolwyck, K. Gustafson. Validated Method for Detection and Direct ELISA Analysis of Cry2Ab2 in Cottonseed. Unpublished study prepared by Monsanto Company.	45750201	Monsanto Company	OWN	Submitted 13-Apr-2001

Signature

Name and Title

Melinda C. McCann
Regulatory Affairs Mgr.

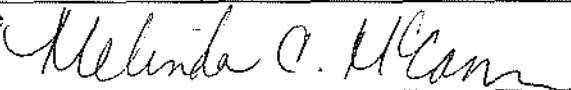
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DATA MATRIX

Date: May 30, 2007			EPA Reg No./File Symbol: 524-522		Page 9 of 26
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167			Product: Bollgard II cotton		
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.2200	Lee, T.C.; J.L. Lee; J.D. Astwood. (2001) Effect of Heat Treatment on the Immunodetection of Cry2Ab2, GUS, Cry1Ac and NPTII Proteins Produced in Cotton Event 15985. MSL-16810. Unpublished study prepared by Monsanto Company.	45750202	Monsanto Company	OWN	Submitted 13-Apr-2001
885.4340	McKee, M.; Fernandez, S. (2002) Endangered Species Impact Assessment for the Cry1Ac and Cry2Ab2 Proteins in Bollgard II Cotton. MSL-17673. Unpublished study prepared by Monsanto Company.	45608901	Monsanto Company	OWN	Submitted 18-Feb-2002
885.4340	Monsanto Company (2002) Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton (<i>Gossypium hirsutum</i> L.). EPA Reg. No 524-LEE, MRID# 45086310; Request for a waiver from the inclusion of information regarding the exposure and toxicity of the Cry2Ab2 protein to parasitic Hymenoptera (<i>Nasonia vitripennis</i>) in the ecological risk assessment.	No MRID assigned	Monsanto Company	OWN	Submitted 18-Apr-2002
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007



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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G.; Reding, H. (2001) Insect Resistance Management Plan for Bollgard II Cotton. Unpublished study prepared by Monsanto Company.	45545701	Monsanto Company	OWN	Submitted 20-Nov-2001
	Burns, J.; Gustafson, K.; Reding, H. (2001) Public Interest Document for Bollgard II Cotton in Support of the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton. Unpublished study prepared by Monsanto Company.	45558801	Monsanto Company	OWN	Submitted 11-Dec-2001
858.1100 858.2200	Bannon, G.; Alibhai, M.; McCoy, R.; Reed, R.; Silvanovich, A. (2002) Safety Assessment of GUS E377K in Bollgard II cotton. MSL-17618. Unpublished study prepared by Monsanto Company.	45601801	Monsanto Company	OWN	Submitted 7-Feb-2002
885.1100 885.1200 885.1300 885.2100	Pineda, N.; Mittanck, D.; Cavato, T.; Lirette, R. (2002) PCR and DNA Sequence Analysis of the Insert in Bollgard II Cotton Event 15985. MSL-17146. Unpublished study prepared by Monsanto Company.	45601802	Monsanto Company	OWN	Submitted 7-Feb-2002
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2002) Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton (<i>Gossypium hirsutum</i> L.). EPA File Symbol: 524-LEE.	No MRID assigned	Monsanto Company	OWN	Submitted 7-Jun-2002
885.1100 885.1200 885.1500	Monsanto Company. (2002) Administrative Materials for Application to Amend the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 Insect Control Protein from a Seed Increase/Plant Propagation approval to Full Commercial Use for Cotton; EPA Reg. No. 524-522.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
885.5200	Dubelman, S.; Ayden, B.; Mueth, M.; Jiang, C.; Brown, C.; Uffman, J.; Duan, J. (2002) Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry2Ab2 Protein Derived from Cotton Leaf Tissue. MSL-16892. Unpublished study prepared by Monsanto Company.	45806601	Monsanto Company	OWN	Submitted 22-Nov-2002
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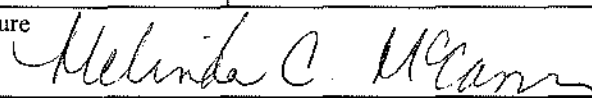
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2002) Request for Clarification of Conditions of Registration of the Plant-Incorporated Protectant, Cry2Ab2 Insect Control Protein in cotton.	No MRID assigned	Monsanto Company	OWN	Submitted 17-July-2002
885.1100 885.1200 885.1500	Monsanto Company (2002) Administrative Materials for Application to Amend the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 Insect Control Protein, from Seed Increase/Plant Propagation to Full Commercial Use for Cotton. 99-CT-858E.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
	Monsanto Company (2002) Responses to EPA questions regarding the Insect Resistance management (IRM) plan for Bollgard II cotton, in support of the registration request for the plant-incorporated protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 insect control protein, as expressed in cotton, EPA Reg. No. 524-522.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Silvanovich, A.; Bannon, G.; Astwood, J. (2002) Bioinformatics Analysis of the Cry1Ac Protein Utilizing an Allergen Sequence Database. MSL-18205. Unpublished study prepared by Monsanto Company.	45903501	Monsanto Company	OWN	Submitted 14-Mar-2003
	Silvanovich, A.; Bannon, G.; Astwood, J. (2002) Bioinformatics Analysis of the Cry1Ac Protein Utilizing Toxin and Public Domain Sequence Databases. MSL-18204. Unpublished study prepared by Monsanto Company.	45920401	Monsanto Company	OWN	Submitted 25-Apr-2003
	Shapple, Z.; Lahman, L. (2002) An Analysis of the Outcrossing Potential of Upland Cotton (<i>Gossypium hirsutum</i> L.) Sprayed with Insecticides Within Field Plots in Northwestern Puerto Rico. MSL-18716. Unpublished study prepared by Monsanto Company.	46008002	Monsanto Company	OWN	Submitted 04-Jun-2003
	Starke, M. (2004) Monsanto Bollgard and Bollgard II Cotton Seed Units Sold in the U.S. in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 29-Jan-2004

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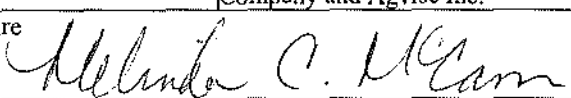
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Lahman, L. (2003) Segregation Data from the Cottonseed Used in the Analysis of the Outcrossing Potential of Upland Cotton (<i>Gossypium hirsutum</i> L.) Sprayed with Insecticides within Field Plots in Northwestern Puerto Rico. 99-CT-858E. Unpublished study prepared by Monsanto Company.	46098101	Monsanto Company	OWN	Submitted 17-Oct-2003
885.2300	Brown, M. (2003) Independent Lab Validation of the Strategic Diagnostics Inc. Seed Cry2Ab Lateral Flow Test Strip Performance Verification for Cottonseed. Unpublished study prepared by Strategic Diagnostics, Inc.	46155401	Monsanto Company	OWN	Submitted 19-Dec-2003
885.2300	Brown, M. (2003) Characterization of Antibody Used in Strategic Diagnostics Inc. Seed Cry2Ab Lateral Flow Strip Test. Unpublished study prepared by Strategic Diagnostics, Inc.	46155402	Monsanto Company	OWN	Submitted 19-Dec-2003
885.5200	Dubelman, S.; Mueh, M.; Jiang, C.; Jiang, C.; Brown, C. (2003) Determination of Soil Concentrations of Cry1Ac and Cry2Ab2 Proteins in Field Plots Planted with Bollgard and Bollgard II Cotton. MSL-17248. Unpublished study prepared by Monsanto Company and Agvise Inc.	46179001	Monsanto Company	OWN	Submitted 21-Jan-2004
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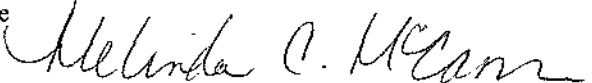
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2004) Submission of a Bollgard II cotton remedial action plan for tobacco budworm and cotton bollworm as of condition of registration (EPA Reg. No 524-522). 99-CT-858E.	No MRID assigned	Monsanto Company	OWN	Submitted 29-Jan-2004
	DiNicola, N.; Starke, M. (2004) 2003 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. Unpublished study prepared by Monsanto Company.	46184401	Monsanto Company	OWN	Submitted 30-Jan-2004
885.1400 885.1500 885.2400 885.2500	Mozaffar, S.; Sayegh, F.; Lirette, R. (2003) Cry2Ab2 Protein Levels in Tissues Collected from Bollgard II Cotton Produced in U.S. Field Trials. MSL-18666. Unpublished study prepared by Monsanto Company.	46222301	Monsanto Company	OWN	Submitted 12-Mar-2004
	Head, G.; Voth, R. (2004) A Final Report on Studies to Assess Production of <i>Helicoverpa zea</i> from Alternate Host Plants and from the External Unsprayed Non-Bt Cotton Refuge for Bollgard Cotton. MSL-19238. Unpublished study prepared by Monsanto Company.	46222401	Monsanto Company	OWN	Submitted 15-Mar-2004
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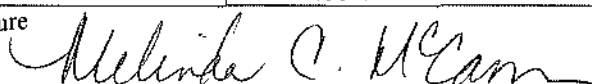
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Unnithan, G.; Brink, S.; Wood, B.; et al. (2004) Susceptibility of Southwestern Pink Bollworm to Cry2Ab2: Baseline responses in 2001 and 2002. Project Number: 99-CT-858E. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46272001	Monsanto Company	OWN	Submitted 13-May-2004
	Greenplate, J. (2004) Report on Studies to Assess Supplemental Pyrethroid Spray Effects on <i>Helicoverpa zea</i> Populations in Bollgard Cotton. MSL-19252. Unpublished study prepared by Monsanto Company.	46222402	Monsanto Company	OWN	Submitted 15-Mar-2004
	Gustafson, D.; Head, G.; Reding, K. (2001) Impact of Effective Refuge Size and Typical Insecticide Use Practices on Model Predictions of Years to Resistance of Tobacco Budworm and Cotton Bollworm to Bollgard Cotton. MSL-19229. Unpublished study prepared by Monsanto Company.	46222403	Monsanto Company	OWN	Submitted 15-Mar-2004
	Gould, F.; Blair, N.; Reid, M.; Rennie, T.; Lopez, J.; Micinski, J. (2002) <i>Bacillus thuringiensis</i> - Toxin Resistance Management: Stable Isotope Assessment of Alternate Host Use by <i>Helicoverpa zea</i> . PNAS 2002 99: 16581-16586.	46242501	Monsanto Company	PL	Submitted 15-Mar-2004
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Agricultural Biotechnology Stewardship Technical Committee (2004) Extent of Corn Earworm (<i>Helioverpa zea</i>) North-South Migration and Impact on Resistance Management for Bt Crops. Unpublished study prepared by Agricultural Biotechnology Stewardship Technical Committee.	46242502	Monsanto Company	OWN	Submitted 15-Mar-2004
	Ali, I.; Luttrell, R. (2004) Baseline Susceptibility of <i>Heliothis virescens</i> and <i>Helioverpa zea</i> to Cry2Ab2. 99-CT-858E. Unpublished study prepared by University of Arkansas.	46272002	Monsanto Company	OWN	Submitted 13-May-2004
	Blanco, C.; Mullen, M. (2004) <i>Bacillus thuringiensis</i> Resistance Monitoring Program for Tobacco Bndworm and Bollworm in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by USDA-ARS-SIMRU.	46272003	Monsanto Company	OWN	Submitted 13-May-2004
	Bhatti, M.; Lahman, L.; Shapiro, J.; et al.; (2004) Monitoring the Effectiveness of Insecticidal Sprays to Limit Outcrossing from Bollgard II Cotton to the Conventional Cotton Planted in Border Rows in a 2003-2004 Puerto Rico Cotton Breeding Nursery: Final Report. MSL-19341 and 99-CT-858E. Unpublished study prepared by Monsanto Company.	46308801	Monsanto Company	OWN	Submitted 29-Jun-2004

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Lahman, L.K. (2004) Supplemental Sales and Acreage Data for Bollgard and Bollgard II Cotton in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 8-Oct-2004
	Monsanto Company. (2004) Response to August 25, 2004 EPA letter regarding Insect Resistance Monitoring, the Compliance Assurance Program Community refuge Program, Grower Education, Remedial Action and Sales Data for the Bollgard and Bollgard II registrations.	No MRID assigned	Monsanto Company	OWN	Submitted 8-Oct-2004
	Monsanto Company. (2004) Submission of the revised remedial action plans for tobacco budworm and cotton bollworm required as conditions of the Bollgard and Bollgard II cotton registrations. 04-CT-133E-2 and 04-CT-134E-2.	No MRID assigned	Monsanto Company	OWN	Submitted 12-Nov-2004

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Dennehy, T.; Unnithan, G.; Brink, S.; et al. (2004) Susceptibility of Southwestern Pink Bollworm to Bt toxins Cry1Ac and Cry2Ab2: Final Results of 2003 Season. 04-CT-133E-2 and 04-CT-134E-2. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46441901	Monsanto Company	OWN	Submitted 20-Dec-2004
	Pester, T.; Starke, M.; DiNicola, N. (2005) The 2004 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E-6 and 04-CT-134E-6. Unpublished study prepared by Monsanto Company.	46457101	Monsanto Company	OWN	Submitted 28-Jan-2005
	Pester, T.; Starke, M. (2005) The 2004 Bollgard and Bollgard II Cotton Community Refuge Program Survey Report and Community Refuge Agreement Forms. 04-CT-133E-7 and 04-CT-134E-7. Unpublished study prepared by Monsanto Company.	46482801	Monsanto Company	OWN	Submitted 28-Jan-2005
	Starke, M. (2005) Monsanto Bollgard II Cotton Seed Units Sold and Estimate of Acres Planted in the U.S. in 2004. 04-CT-134E-4. Unpublished study prepared by Monsanto Company.	46483401	Monsanto Company	OWN	Submitted 28-Jan-2005

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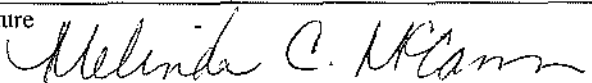


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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Blanco, C. (2005) <i>Bacillus thuringiensis</i> Cry1Ac/Cry2Ab2 Resistance Monitoring Program for Tobacco Budworm and Bollworm in 2004. 04-CT-133E-11 and 04-CT-134-11. Unpublished study prepared by USDA-ARS-SIMRU.	46547601	Monsanto Company	OWN	Submitted 13-May-2005
	Ali, I.; Luttrell, R. (2005) Baseline Susceptibility of <i>Heliothis virescens</i> to Cry2Ab2: Final Report. 04-CT-133E-11. Unpublished study prepared by University of Arkansas.	46547602	Monsanto Company	OWN	Submitted 13-May-2005
885.1100 885.1200 885.1500	Monsanto Company (2005) Submission of revised Confidential Statement of Formula (CSF) and final printed labels for Bollgard II cotton (EPA Reg. No. 524-522). 04-CT-133E-13.	No MRID assigned	Monsanto Company	OWN	Submitted 3-Oct-2005
	Monsanto Company (2005) Request to Amend the Conditions of Registration for Bollgard II cotton. 04-CT-133E-15.	No MRID assigned	Monsanto Company	OWN	Submitted 15-Nov-2005
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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DATA MATRIX

Date: May 30, 2007
EPA Reg No./File Symbol: 524-522 Page 21 of 26
Applicant's/Registrant's Name & Address:
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167
Product: Bollgard II cotton
Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1400 885.2250	Head, G.; Gustafson, D. (2005) Production of Tobacco Budworm from Alternative Host Plants and the Role of These Host Plants as Natural Refuge for Bollgard II Cotton. 04-CT-113E-17, 04-01-36-04, and MSL-20123. Unpublished study prepared by Monsanto Company.	46717201	Monsanto Company	OWN	Submitted 20-Dec-2005
	Gustafson, D.; Head, G. (2005) Modeling the Impact of Natural Refuge on the Evolution of Tobacco Budworm and Cotton Bollworm Resistance to Bollgard II Cotton. 04-CT-133E-17 and MSL-19689. Unpublished study prepared by Monsanto Company.	46717202	Monsanto Company	OWN	Submitted 20-Dec-2005
	Head, G.; McCann, M.; Mullins, J. (2005) Scientific and Economic Justification for Not Requiring Structured Cotton Refuges for Bollgard II Cotton in the U.S. Cotton Belt from Texas to the East Coast. 04-CT-133E-17 and MSL-20091. Unpublished study prepared by Monsanto Company.	46717203	Monsanto Company	OWN	Submitted 20-Dec-2005
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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DATA MATRIX

Date: May 30, 2007 EPA Reg No./File Symbol: 524-522 Page 22 of 26

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAC and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Dennehy, T.; Unnithan, G.; Brink, S.; et al. (2005) Susceptibility to Bt Toxins CryIAC and Cry2Ab2 of Southwestern Pink Bollworm in 2004. 04-CT-133E-16 and 04-CT-134E-16. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46735001	Monsanto Company	OWN	Submitted 20-Dec-2005
	Bookout, J. (2006) 2005 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E-21 and 04-CT-134E-21. Unpublished study prepared by Monsanto Company.	46745501	Monsanto Company	OWN	Submitted 27-Jan-2006
	McCann, M.; Whittle, M. (2006) 2005 Bollgard and Bollgard II Cotton Community Refuge Program Report. 04-CT-133E-18 and 04-CT-134E-18. Unpublished study prepared by Monsanto Company.	46754701	Monsanto Company	OWN	Submitted 27-Jan-2006
	McCann, M.; Whittle, M. (2006) Bollgard II Cotton Seed Units Sold in the U.S. in 2005. 04-CT-133E-19. Unpublished study prepared by Monsanto Company.	46754801	Monsanto Company	OWN	Submitted 27-Jan-2006

Signature

Name and Title
Melinda C. McCann
Regulatory Affairs Mgr.

Date
May 30, 2007



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DATA MATRIX


Date: May 30, 2007 EPA Reg No./File Symbol: 524-522 Page 23 of 26

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 3-Apr-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 7-Apr-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 10-May-2006
	Blanco, C. (2006) <i>Bacillus thuringiensis</i> CryIAc and Cry2Ab2 Resistance Monitoring Program in Field-Collected Tobacco Budworm and Bollworm in 2005 - Annual Report. 04-CT-133E-22 and 04-CT-134E-22. Unpublished study prepared by Monsanto Company.	46826601	Monsanto Company	OWN	Submitted 10-May-2006
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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DATA MATRIX

Date: May 30, 2007
Applicant's/Registrant's Name & Address:
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167
EPA Reg No./File Symbol: 524-522
Product: Bollgard II cotton
Page 24 of 26

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Ali, I.; Luttrell, R. (2006) Susceptibles of <i>Heliothis virescens</i> and <i>Helicoverpa zea</i> to Cry2Ab2 Insecticidal Protein in Diet Incorporated Assays Conducted in 2005. 04-CT-133E-22 and 04-CT-134E-22. Unpublished study prepared by University of Arkansas.	46826602	Monsanto Company	OWN	Submitted 10-May-2006
885.1400 885.2250	Head, G. (2006) Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts for Monsanto's Bollgard II Cotton. 06-RA-36-02 and 04-CT-133E-12. Unpublished study prepared by Monsanto Company.	46982001	Monsanto Company	OWN	Submitted 10-Nov-2006
	Dennehy, T.; Unnithan, G.; Harpold, V.; et al. (2006) Susceptibility of Southwestern Pink Bollworm to Bt Toxins CryIAc and Cry2Ab2 in 2005: Bollgard and Bollgard II Cotton. 04-CT-133E-26 and 04-CT-134E-26. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	47021601	Monsanto Company	OWN	Submitted 15-Dec-2006
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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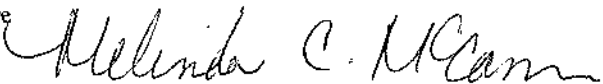


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DATA MATRIX

Date: May 30, 2007		EPA Reg No./File Symbol: 524-522		Page 25 of 26	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	McCann, M.C. and Carden, J.A. (2007) Bollgard II Cotton Seed Units Sold in the U.S. in 2006. 04-CT-133E-28. Unpublished study prepared by Monsanto Company.	47042801	Monsanto Company	OWN	Submitted 29-Jan-2007
	Reding, K.; Carden, J. (2007) 2006 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E and 04-CT-134E. Unpublished study prepared by Monsanto Company.	47042701	Monsanto Company	OWN	Submitted 29-Jan-2007
885.2250	Head, G.; Orth, R. (2007) Independent Laboratory Validation and Publication of Gossypol Determination Method for Adult Lepidoptera. 04-CT-133E-29. Unpublished study prepared by Covance Laboratories, Inc.	47059101	Monsanto Company	OWN	Submitted 14-Feb-2007
	Monsanto Company (2007) Follow up from EPA BPPD and Monsanto Company meeting regarding the planting restriction in Texas for Bollgard and Bollgard II cotton (EPA Reg. Nos. 524-478 and 524-522).	47101000	Monsanto Company	OWN	Submitted 6-Apr-2007
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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DATA MATRIX

Date: May 30, 2007 EPA Reg No./File Symbol: 524-522 Page 26 of 26

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	McCann, M. (2007) Bollgard and Bollgard II Cotton Seed Units Sold in 10 Texas Countries from 1998 to 2006. 04-CT-133E-30 and 04-CT-134E-30. Unpublished study prepared by Monsanto Company.	47101001	Monsanto Company	OWN	Submitted 6-Apr-2007
	Head, G. (2007) Determination of No Harm from Bollgard and Bollgard II Cotton Plantings in 10 Restricted Texas Countries. 04-CT-133E-30 and 04-CT-134E-30. Unpublished study prepared by Monsanto Company.	47101002	Monsanto Company	OWN	Submitted 6-Apr-2007
	Monsanto Company (2007) Information requested by EPA BPPD in support of the registrations for Bollgard and Bollgard II cotton (EPA Reg. Nos. 524-478 and 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 17-Apr-2007
	Head, G.P. and Gustafson, D.I. (2007) Monsanto's Response to U.S. EPA Questions on Natural Refuge Modeling and Statistical Analysis. 04-CT-133E-20. Unpublished study prepared by Monsanto Company.	Not assigned yet	Monsanto Company	OWN	Submitted 16-May-2007

Signature

Name and Title
Melinda C. McCann
Regulatory Affairs Mgr.

Date
May 30, 2007

ROUTING & TRANSMITTAL SLIP

ay 31, 2007

TO: (Name, office symbol, room number, building, Agency/Post)

Initials

Date

1. Sheryl Reilly

2. Janet Andersen

3.

3

Action	File	Note And Return
X Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	X Signature
Coordination	Justify	Concurrence

REMARKS

Bollgard II Natural Refuge Unconditional Approval

URGENT: The data matrix did not list Cry1Ac and Cry2Ab2 human health data. Russ will be sending a revised matrix PDF via email tomorrow.

Also note that FIFRA 6(e) language was not placed in this 3(c)(5) unconditional registration notice because section 6(e) of FIFRA pertains to section 3(c)(7). My understanding is that when the registration was converted to an unconditional registration in 2006, that this necessitates that any cancellation proceedings would fall under FIFRA section 6(b).

Should you need to get a hold of me tomorrow, my cell number is [REDACTED]

FROM: (Name, org. symbol, Agency/Post)

Room No.-Bldg.

Mike Mendelsohn

Phone No
308-8715

Personal privacy information

BPPD# 1159

MONSANTO



MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005-7211
PHONE (202) 783-2460
FAX (202) 789-1819
<http://www.monsanto.com>

May 31, 2007

Document Processing Desk (AMEND)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

Attention: Dr. Sheryl Reilly, Team Leader 92

Subject: Response to Pre-Acceptance Letter
Bollgard® II cotton, EPA Reg. No. 524-522;

Dear Dr. Reilly,

Monsanto herewith accepts the conditions set forth in the Agency's pre-acceptance letter dated May 30, 2007. In addition to accepting the conditions of registration, Monsanto is submitting a Certification with Respect to Citation of Data (EPA Form 8570-34), a Data Matrix (EPA Form 8570-35), and revised label for Bollgard II cotton, EPA Reg. No. 524-522, as required by EPA. We ask that EPA continue the registration process per our request to amend the registration for Bollgard II cotton to include implementation of a natural refuge.

If you have any questions or comments regarding this response, please feel free to contact me at 202/383-2866.

Sincerely,


Russell P. Schneider, Ph.D.
Director, Regulatory Affairs

Please read instructions on reverse before completing form.

Form Approved, OMB No. 2070-0060. Approval Expires 2-28-95



United States
Environmental Protection Agency
 Washington, DC 20460

☐ **Registration**
☐ **Amendment**
☒ **Other**

OPP Identifier
 Number

Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 524-522	2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Bollgard II cotton	PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of data matrix in support of Bollgard II cotton registration (EPA Reg. No. 524-522).

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled <input type="checkbox"/> Other			

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Dr. Russell P. Schneider		Title Regulatory Affairs Director		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Melinda C. McCann</i>		3. Title Regulatory Affairs Manager			
4. Typed Name Melinda C. McCann Tel. (314) 694-7556		5. Date May 30, 2007			



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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 (202) 383-2866

EPA Registration Number / File Symbol:

Reg. No. 524-522

Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* CryIAC and Cry2Ab2 proteins and the genetic material necessary for their production in cotton

Date:

May 30, 2007

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:

Terrestrial field crop

Product Name:

Bollgard II cotton

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies set offers of compensation (the Data Matrix Form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY



[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-in response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.



I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

May 30, 2007

Typed or Printed Name and Title

Melinda C. McCann, Regulatory Affairs
Manager



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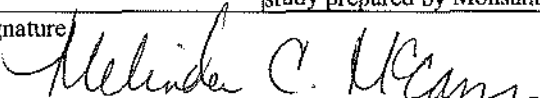
Page 1 of 23

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1400 885.1500 885.2400 885.2500	Kolwyck, D; Hamilton, K; Reed, A. (1999) GUS Protein Levels in Insect Protected Cotton Samples Produced in the U.S. Field Trials. MSL-16097. Unpublished study prepared by Monsanto Company.	44939402	Monsanto Company	OWN	Submitted 30-Sep-1999
885.1400 885.1500 885.2400 885.2500	Kolwyck, D; K Hamilton; and A Reed. (1999) Protein Levels in Insect Protected Cotton Samples Produced in the 1998 U.S. Field Trials. MSL-16612. Unpublished study prepared by Monsanto Company.	44966601	Monsanto Company	OWN	Submitted 5-Nov-1999
885.1100 885.1200 885.1500	Monsanto Company. (2000) Administrative Materials in Support of the Request for the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Corn (<i>Zea mays</i> L.) and Cotton (<i>Gossypium hirsutum</i> L.).	45086300	Monsanto Company	OWN	Submitted 4-Apr-2000
	Hamilton, K.; Reed, A. (1999) Field Report: Production of Tissue Samples from Insect Protected Cotton Events Grown in the 1998 U.S. Field Season. MSL-16019. Unpublished study prepared by Monsanto Company.	45086301	Monsanto Company	OWN	Submitted 4-Apr-2000
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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Date: May 30, 2007

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1300 885.2100	Doherty, S.; Hamilton, K.A.; Lirette, R.P.; Borovkova, I. (2000) Amended Report for Molecular Characterization of Cotton Event 15985. MSL-16620. Unpublished study prepared by Monsanto Company.	45086303	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4380	Maggi, V. (2000). Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Honey Bee Larvae. MSL-16175, CA-99-059, and CAR 157-99. Unpublished study prepared by California Agricultural Research.	45086307	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4380	Maggi, V. (2000) Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (<i>Apis mellifera</i> L.). 99-858E, CA-99-058, and CAR 156-99. Unpublished study prepared by California Agricultural Research.	45086308	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with Green Lacewing Larvae (<i>Chrysoperla carnea</i>). MSL-16171 and WL-99-061. Unpublished study prepared by Wildlife International Ltd.	45086309	Monsanto Company	OWN	Submitted 4-Apr-2000

Signature

Name and Title
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Date
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-16173 and WL-99-062. Unpublished study prepared by Wildlife International Ltd.	45086310	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16172 and WL-99-060. Unpublished study prepared by Wildlife International Ltd.	45086311	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. 99-858E, 139-445, and WL-99-067. Unpublished study prepared by Wildlife International Ltd.	45086313	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Teixiera, D. (2000) Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (<i>Folsomia candida</i>): Amended Final Report. MSL-16174 and SB-99-063. Unpublished study prepared by Springbom Laboratories, Inc.	45086314	Monsanto Company	OWN	Submitted 4-Apr-2000
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.; Grimcs, J.; Beavers, J. (2000) Insect Protection Protein 2 in Cottonseed Meal: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16178. Unpublished study prepared by Wildlife International, Ltd.	45086316	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4200	Li, M.; Robinson, E. (2000) Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish. MSL-16179. Unpublished study prepared by Thad Cochran National Warmwater Aquaculture Center.	45086318	Monsanto Company	OWN	Submitted 4-Apr-2000
885.5200	Dubelman, S.; Martin, J.; Bhalgat, M. (2001) Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Insect Protein 2 in Cotton Leaf Tissue. MSL-16185. Unpublished study prepared by PTRL East, Inc. and Monsanto Company.	45337101	Monsanto Company	OWN	Submitted 21-Feb-2001
885.4380	Maggi, V. (2000) Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein on Honey Bee Larvae. MSL-16961. Unpublished study prepared by California Agricultural Research, Inc.	45337102	Monsanto Company	OWN	Submitted 21-Feb-2001
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4200	Li, M.; Robinson, E. (2001) Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish. Amended MSL-16179. Unpublished study prepared by Thad Cochran National Warmwater Aquaculture Center.	45337103	Monsanto Company	OWN	Submitted 21-Feb-2001
885.1100 885.1200 885.1300 885.2100	Doherty, S.; Lirette, R.; Hamilton, K. (2000) Molecular Analysis of the Stability of Cotton Event 15985. MSL-16749. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 21-Feb-2001
885.2300	D. Kolwyck, K. Gustafson. Validated Method for Detection and Direct ELISA Analysis of Cry2Ab2 in Cottonseed. Unpublished study prepared by Monsanto Company.	45750201	Monsanto Company	OWN	Submitted 13-Apr-2001
885.1100 885.2200	Lee, T.C.; J.L. Lee; J.D. Astwood. (2001) Effect of Heat Treatment on the Immunodetection of Cry2Ab2, GUS, Cry1Ac and NPTII Proteins Produced in Cotton Event 15985. MSL-16810. Unpublished study prepared by Monsanto Company.	45750202	Monsanto Company	OWN	Submitted 13-Apr-2001
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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167
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Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G.; Reding, H. (2001) Insect Resistance Management Plan for Bollgard II Cotton. Unpublished study prepared by Monsanto Company.	45545701	Monsanto Company	OWN	Submitted 20-Nov-2001
	Burns, J.; Gustafson, K.; Reding, H. (2001) Public Interest Document for Bollgard II Cotton in Support of the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton. Unpublished study prepared by Monsanto Company.	45558801	Monsanto Company	OWN	Submitted 11-Dec-2001
858.1100 858.2200	Bannon, G.; Alibhai, M.; McCoy, R.; Reed, R.; Silvanovich, A. (2002) Safety Assessment of GUS E377K in Bollgard II cotton. MSL-17618. Unpublished study prepared by Monsanto Company.	45601801	Monsanto Company	OWN	Submitted 7-Feb-2002
885.1100 885.1200 885.1300 885.2100	Pineda, N.; Mittanck, D.; Cavato, T.; Lirette, R. (2002) PCR and DNA Sequence Analysis of the Insert in Bollgard II Cotton Event 15985. MSL-17146. Unpublished study prepared by Monsanto Company.	45601802	Monsanto Company	OWN	Submitted 7-Feb-2002

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	McKee, M.; Fernandez, S. (2002) Endangered Species Impact Assessment for the Cry1Ac and Cry2Ab2 Proteins in Bollgard II Cotton. MSL-17673. Unpublished study prepared by Monsanto Company.	45608901	Monsanto Company	OWN	Submitted 18-Feb-2002
885.4340	Monsanto Company (2002) Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton (<i>Gossypium hirsutum</i> L.). EPA Reg. No 524-LEE, MRID# 45086310; Request for a waiver from the inclusion of information regarding the exposure and toxicity of the Cry2Ab2 protein to parasitic Hymenoptera (<i>Nasonia vitripennis</i>) in the ecological risk assessment.	No MRID assigned	Monsanto Company	OWN	Submitted 18-Apr-2002
	Monsanto Company (2002) Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton (<i>Gossypium hirsutum</i> L.). EPA File Symbol: 524-LEE.	No MRID assigned	Monsanto Company	OWN	Submitted 7-Jun-2002
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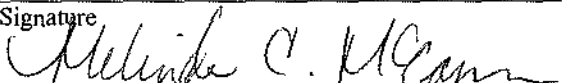
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2002) Request for Clarification of Conditions of Registration of the Plant-Incorporated Protectant, Cry2Ab2 Insect Control Protein in cotton.	No MRID assigned	Monsanto Company	OWN	Submitted 17-July-2002
885.1100 885.1200 885.1500	Monsanto Company (2002) Administrative Materials for Application to Amend the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 Insect Control Protein, from Seed Increase/Plant Propagation to Full Commercial Use for Cotton. 99-CT-858E.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
	Monsanto Company (2002) Responses to EPA questions regarding the Insect Resistance management (IRM) plan for Bollgard II cotton, in support of the registration request for the plant-incorporated protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 insect control protein, as expressed in cotton, EPA Reg. No. 524-522.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1500	Monsanto Company. (2002) Administrative Materials for Application to Amend the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 Insect Control Protein from a Seed Increase/Plant Propagation approval to Full Commercial Use for Cotton; EPA Reg. No. 524-522.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
885.5200	Dubelman, S.; Ayden, B.; Mueth, M.; Jiang, C.; Brown, C.; Uffman, J.; Duan, J. (2002) Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry2Ab2 Protein Derived from Cotton Leaf Tissue. MSL-16892. Unpublished study prepared by Monsanto Company.	45806601	Monsanto Company	OWN	Submitted 22-Nov-2002
	Shappley, Z.; Lahman, L. (2002) An Analysis of the Outcrossing Potential of Upland Cotton (<i>Gossypium hirsutum</i> L.) Sprayed with Insecticides Within Field Plots in Northwestern Puerto Rico. MSL-18716. Unpublished study prepared by Monsanto Company.	46008002	Monsanto Company	OWN	Submitted 04-Jun-2003

Signature

Name and Title

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Regulatory Affairs Mgr.

Date

May 30, 2007



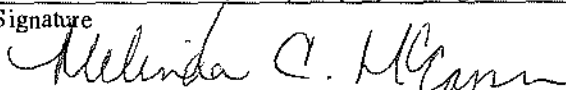
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Lahman, L. (2003) Segregation Data from the Cottonseed Used in the Analysis of the Outcrossing Potential of Upland Cotton (<i>Gossypium hirsutum</i> L.) Sprayed with Insecticides within Field Plots in Northwestern Puerto Rico. 99-CT-858E. Unpublished study prepared by Monsanto Company.	46098101	Monsanto Company	OWN	Submitted 17-Oct-2003
885.2300	Brown, M. (2003) Independent Lab Validation of the Strategic Diagnostics Inc. Seed Cry2Ab Lateral Flow Test Strip Performance Verification for Cottonseed. Unpublished study prepared by Strategic Diagnostics, Inc.	46155401	Monsanto Company	OWN	Submitted 19-Dec-2003
885.2300	Brown, M. (2003) Characterization of Antibody Used in Strategic Diagnostics Inc. Seed Cry2Ab Lateral Flow Strip Test. Unpublished study prepared by Strategic Diagnostics, Inc.	46155402	Monsanto Company	OWN	Submitted 19-Dec-2003
885.5200	Dubelman, S.; Mueth, M.; Jiang, C.; Jiang, C.; Brown, C. (2003) Determination of Soil Concentrations of CryIAc and Cry2Ab2 Proteins in Field Plots Planted with Bollgard and Bollgard II Cotton. MSL-17248. Unpublished study prepared by Monsanto Company and Agvise Inc.	46179001	Monsanto Company	OWN	Submitted 21-Jan-2004
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Starke, M. (2004) Monsanto Bollgard and Bollgard II Cotton Seed Units Sold in the U.S. in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 29-Jan-2004
	DiNicola, N.; Starke, M. (2004) 2003 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. Unpublished study prepared by Monsanto Company.	46184401	Monsanto Company	OWN	Submitted 30-Jan-2004
885.1400 885.1500 885.2400 885.2500	Mozaffar, S.; Sayegh, F.; Lirette, R. (2003) Cry2Ab2 Protein Levels in Tissues Collected from Bollgard II Cotton Produced in U.S. Field Trials. MSL-18666. Unpublished study prepared by Monsanto Company.	46222301	Monsanto Company	OWN	Submitted 12-Mar-2004
	Head, G.; Voth, R. (2004) A Final Report on Studies to Assess Production of <i>Helicoverpa zea</i> from Alternate Host Plants and from the External Unsprayed Non-Bt Cotton Refuge for Bollgard Cotton. MSL-19238. Unpublished study prepared by Monsanto Company.	46222401	Monsanto Company	OWN	Submitted 15-Mar-2004
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Greenplate, J. (2004) Report on Studies to Assess Supplemental Pyrethroid Spray Effects on <i>Helicoverpa zea</i> Populations in Bollgard Cotton. MSL-19252. Unpublished study prepared by Monsanto Company.	46222402	Monsanto Company	OWN	Submitted 15-Mar-2004
	Gustafson, D.; Head, G.; Reding, K. (2001) Impact of Effective Refuge Size and Typical Insecticide Use Practices on Model Predictions of Years to Resistance of Tobacco Budworm and Cotton Bollworm to Bollgard Cotton. MSL-19229. Unpublished study prepared by Monsanto Company.	46222403	Monsanto Company	OWN	Submitted 15-Mar-2004
	Gould, F.; Blair, N.; Reid, M.; Rennie, T.; Lopez, J.; Micinski, J. (2002) <i>Bacillus thuringiensis</i> - Toxin Resistance Management: Stable Isotope Assessment of Alternate Host Use by <i>Helicoverpa zea</i> . PNAS 2002 99: 16581-16586.	46242501	Monsanto Company	PL	Submitted 15-Mar-2004
	Agricultural Biotechnology Stewardship Technical Committee (2004) Extent of Corn Earworm (<i>Helicoverpa zea</i>) North-South Migration and Impact on Resistance Management for BI Crops. Unpublished study prepared by Agricultural Biotechnology Stewardship Technical Committee.	46242502	Monsanto Company	OWN	Submitted 15-Mar-2004
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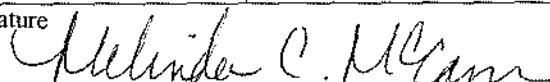
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Unnithan, G.; Brink, S.; Wood, B.; et al. (2004) Susceptibility of Southwestern Pink Bollworm to Cry2Ab2: Baseline responses in 2001 and 2002. Project Number: 99-CT-858E. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46272001	Monsanto Company	OWN	Submitted 13-May-2004
	Ali, I.; Luttrell, R. (2004) Baseline Susceptibility of <i>Heliothis virescens</i> and <i>Helicoverpa zea</i> to Cry2Ab2. 99-CT-858E. Unpublished study prepared by University of Arkansas.	46272002	Monsanto Company	OWN	Submitted 13-May-2004
	Blanco, C.; Mullen, M. (2004) <i>Bacillus thuringiensis</i> Resistance Monitoring Program for Tobacco Budworm and Bollworm in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by USDA-ARS-SIMRU.	46272003	Monsanto Company	OWN	Submitted 13-May-2004
	Monsanto Company (2004) Submission of a Bollgard II cotton remedial action plan for tobacco budworm and cotton bollworm as of condition of registration (EPA Reg. No 524-522). 99-CT-858E.	No MRID assigned	Monsanto Company	OWN	Submitted 29-Jan-2004
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	



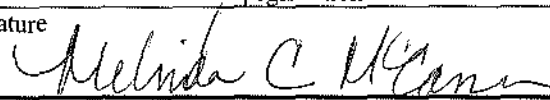
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DATA MATRIX

Date: May 30, 2007		EPA Reg No./File Symbol: 524-522		Page 14 of 23	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Bhatti, M.; Lahman, L.; Shapiro, J.; et al.; (2004) Monitoring the Effectiveness of Insecticidal Sprays to Limit Outcrossing from Bollgard II Cotton to the Conventional Cotton Planted in Border Rows in a 2003-2004 Puerto Rico Cotton Breeding Nursery: Final Report, MSL-19341 and 99-CT-858E. Unpublished study prepared by Monsanto Company.	46308801	Monsanto Company	OWN	Submitted 29-Jun-2004
	Lahman, L.K. (2004) Supplemental Sales and Acreage Data for Bollgard and Bollgard II Cotton in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 8-Oct-2004
	Monsanto Company. (2004) Response to August 25, 2004 EPA letter regarding Insect Resistance Monitoring, the Compliance Assurance Program Community refuge Program, Grower Education, Remedial Action and Sales Data for the Bollgard and Bollgard II registrations.	No MRID assigned	Monsanto Company	OWN	Submitted 8-Oct-2004
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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DATA MATRIX

Date: May 30, 2007		EPA Reg No./File Symbol: 524-522		Page 15 of 23	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company. (2004) Submission of the revised remedial action plans for tobacco budworm and cotton bollworm required as conditions of the Bollgard and Bollgard II cotton registrations. 04-CT-133E-2 and 04-CT-134E-2.	No MRID assigned	Monsanto Company	OWN	Submitted 12-Nov-2004
	Dennehy, T.; Unnithan, G.; Brink, S.; et al. (2004) Susceptibility of Southwestern Pink Bollworm to Bt toxins Cry1Ac and Cry2Ab2: Final Results of 2003 Season. 04-CT-133E-2 and 04-CT-134E-2. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46441901	Monsanto Company	OWN	Submitted 20-Dec-2004
	Pester, T.; Starke, M.; DiNicola, N. (2005) The 2004 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E-6 and 04-CT-134E-6. Unpublished study prepared by Monsanto Company.	46457101	Monsanto Company	OWN	Submitted 28-Jan-2005
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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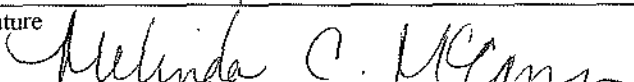
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pester, T.; Starke, M. (2005) The 2004 Bollgard and Bollgard II Cotton Community Refuge Program Survey Report and Community Refuge Agreement Forms. 04-CT-133E-7 and 04-CT-134E-7. Unpublished study prepared by Monsanto Company.	46482801	Monsanto Company	OWN	Submitted 28-Jan-2005
	Starke, M. (2005) Monsanto Bollgard II Cotton Seed Units Sold and Estimate of Acres Planted in the U.S. in 2004. 04-CT-134E-4. Unpublished study prepared by Monsanto Company.	46483401	Monsanto Company	OWN	Submitted 28-Jan-2005
	Blanco, C. (2005) <i>Bacillus thuringiensis</i> Cry1Ac/Cry2Ab2 Resistance Monitoring Program for Tobacco Budworm and Bollworm in 2004. 04-CT-133E-11 and 04-CT-134-11. Unpublished study prepared by USDA-ARS-SIMRU.	46547601	Monsanto Company	OWN	Submitted 13-May-2005
	Ali, I.; Luttrell, R. (2005) Baseline Susceptibility of <i>Heliothis virescens</i> to Cry2Ab2: Final Report. 04-CT-133E-11. Unpublished study prepared by University of Arkansas.	46547602	Monsanto Company	OWN	Submitted 13-May-2005
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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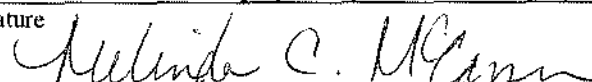
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DATA MATRIX

Date: May 30, 2007
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167
EPA Reg No./File Symbol: 524-522 Page 17 of 23
Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1500	Monsanto Company (2005) Submission of revised Confidential Statement of Formula (CSF) and final printed labels for Bollgard II cotton (EPA Reg. No. 524-522). 04-CT-133E-13.	No MRID assigned	Monsanto Company	OWN	Submitted 3-Oct-2005
	Monsanto Company (2005) Request to Amend the Conditions of Registration for Bollgard II cotton. 04-CT-133E-15.	No MRID assigned	Monsanto Company	OWN	Submitted 15-Nov-2005
885.1400 885.2250	Head, G.; Gustafson, D. (2005) Production of Tobacco Budworm from Alternative Host Plants and the Role of These Host Plants as Natural Refuge for Bollgard II Cotton. 04-CT-113E-17, 04-01-36-04, and MSL-20123. Unpublished study prepared by Monsanto Company.	46717201	Monsanto Company	OWN	Submitted 20-Dec-2005
	Gustafson, D.; Head, G. (2005) Modeling the Impact of Natural Refuge on the Evolution of Tobacco Budworm and Cotton Bollworm Resistance to Bollgard II Cotton. 04-CT-133E-17 and MSL-19689. Unpublished study prepared by Monsanto Company.	46717202	Monsanto Company	OWN	Submitted 20-Dec-2005
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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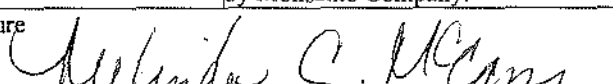
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G.; McCann, M.; Mullins, J. (2005) Scientific and Economic Justification for Not Requiring Structured Cotton Refuges for Bollgard II Cotton in the U.S. Cotton Belt from Texas to the East Coast. 04-CT-133E-17 and MSL-20091. Unpublished study prepared by Monsanto Company.	46717203	Monsanto Company	OWN	Submitted 20-Dec-2005
	Dennehy, T.; Unnithan, G.; Brink, S.; et al. (2005) Susceptibility to Bt Toxins Cry1Ac and Cry2Ab2 of Southwestern Pink Bollworm in 2004. 04-CT-133E-16 and 04-CT-134E-16. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46735001	Monsanto Company	OWN	Submitted 20-Dec-2005
	Bookout, J. (2006) 2005 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E-21 and 04-CT-134E-21. Unpublished study prepared by Monsanto Company.	46745501	Monsanto Company	OWN	Submitted 27-Jan-2006
	McCann, M.; Whittle, M. (2006) 2005 Bollgard and Bollgard II Cotton Community Refuge Program Report. 04-CT-133E-18 and 04-CT-134E-18. Unpublished study prepared by Monsanto Company.	46754701	Monsanto Company	OWN	Submitted 27-Jan-2006
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	



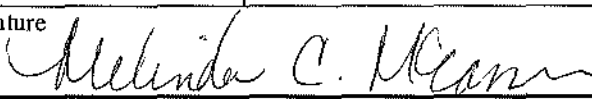
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DATA MATRIX

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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	McCann, M.; Whittle, M. (2006) Bollgard II Cotton Seed Units Sold in the U.S. in 2005. 04-CT-133E-19. Unpublished study prepared by Monsanto Company.	46754801	Monsanto Company	OWN	Submitted 27-Jan-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 3-Apr-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 7-Apr-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 10-May-2006
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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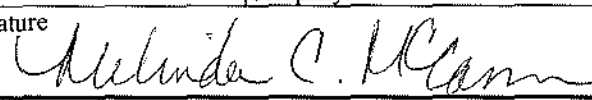
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Blanco, C. (2006) <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 Resistance Monitoring Program in Field-Collected Tobacco Budworm and Bollworm in 2005 - Annual Report. 04-CT-133E-22 and 04-CT-134E-22. Unpublished study prepared by Monsanto Company.	46826601	Monsanto Company	OWN	Submitted 10-May-2006
	Ali, I.; Luttrell, R. (2006) Susceptibles of <i>Heliothis virescens</i> and <i>Helicoverpa zea</i> to Cry2Ab2 Insecticidal Protein in Diet Incorporated Assays Conducted in 2005. 04-CT-133E-22 and 04-CT-134E-22. Unpublished study prepared by University of Arkansas.	46826602	Monsanto Company	OWN	Submitted 10-May-2006
885.1400 885.2250	Head, G. (2006) Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts for Monsanto's Bollgard II Cotton. 06-RA-36-02 and 04-CT-133E-12. Unpublished study prepared by Monsanto Company.	46982001	Monsanto Company	OWN	Submitted 10-Nov-2006
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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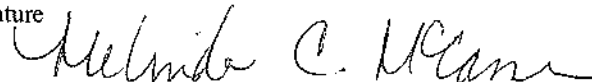
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Date: May 30, 2007		EPA Reg No./File Symbol: 524-522		Page 21 of 23	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Dennehy, T.; Unnithan, G.; Harpold, V.; et al. (2006) Susceptibility of Southwestern Pink Bollworm to Bt Toxins Cry1Ac and Cry2Ab2 in 2005: Bollgard and Bollgard II Cotton. 04-CT-133E-26 and 04-CT-134E-26. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	47021601	Monsanto Company	OWN	Submitted 15-Dec-2006
	McCann, M.C. and Carden, J.A. (2007) Bollgard II Cotton Seed Units Sold in the U.S. in 2006. 04-CT-133E-28. Unpublished study prepared by Monsanto Company.	47042801	Monsanto Company	OWN	Submitted 29-Jan-2007
	Reding, K.; Carden, J. (2007) 2006 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E and 04-CT-134E. Unpublished study prepared by Monsanto Company.	47042701	Monsanto Company	OWN	Submitted 29-Jan-2007
885.2250	Head, G.; Orth, R. (2007) Independent Laboratory Validation and Publication of Gossypol Determination Method for Adult Lepidoptera. 04-CT-133E-29. Unpublished study prepared by Covance Laboratories, Inc.	47059101	Monsanto Company	OWN	Submitted 14-Feb-2007
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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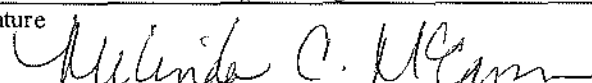
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2007) Follow up from EPA BPPD and Monsanto Company meeting regarding the planting restriction in Texas for Bollgard and Bollgard II cotton (EPA Reg. Nos. 524-478 and 524-522).	47101000	Monsanto Company	OWN	Submitted 6-Apr-2007
	McCann, M. (2007) Bollgard and Bollgard II Cotton Seed Units Sold in 10 Texas Counties from 1998 to 2006. 04-CT-133E-30 and 04-CT-134E-30. Unpublished study prepared by Monsanto Company.	47101001	Monsanto Company	OWN	Submitted 6-Apr-2007
	Head, G. (2007) Determination of No Harm from Bollgard and Bollgard II Cotton Plantings in 10 Restricted Texas Counties. 04-CT-133E-30 and 04-CT-134E-30. Unpublished study prepared by Monsanto Company.	47101002	Monsanto Company	OWN	Submitted 6-Apr-2007
	Monsanto Company (2007) Information requested by EPA BPPD in support of the registrations for Bollgard and Bollgard II cotton (EPA Reg. Nos. 524-478 and 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 17-Apr-2007
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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Date: May 30, 2007 EPA Reg No./File Symbol: 524-522 Page 23 of 23

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G.P. and Gustafson, D.I. (2007) Monsanto's Response to U.S. EPA Questions on Natural Refuge Modeling and Statistical Analysis. 04-CT-133E-20. Unpublished study prepared by Monsanto Company.	Not assigned yet	Monsanto Company	OWN	Submitted 16-May-2007

Signature

Name and Title

Melinda C. McCann
Regulatory Affairs Mgr.

Date

May 30, 2007

Bollgard II® Cotton

Bacillus thuringiensis subsp. *kurstaki* Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production
[PV-GHBK11] in event MON 15985 cotton 0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production
[PV-GHBK04] in event MON 15985 cotton 0.00004 - 0.00052%*

Other Ingredients:

Substance produced by the marker genes and the genetic material necessary for their production
[PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton..... 0.0022-0.0304%*

*Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

® Bollgard II is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the above listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins are planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. Bollgard II must not be planted nor sold ~~Not~~ for commercial planting in Hawaii, Puerto Rico, U.S. Virgin Islands, south of Route 60 (near Tampa) in Florida, and in the following counties in the Texas panhandle, ~~which historically are not cotton producing counties~~: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

[consolidated statements in #4 above] ~~The following information regarding commercial production must be included in the Grower Guide:~~

- a) ~~No planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.~~

- ~~b) Commercial culture of Bollgard II cotton is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.~~

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of Bollgard II cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be

managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

~~Plant at least 5 acres of non-*B.t.k.* cotton (refuge cotton) for every 95 acres of Bollgard II cotton. The refuge cotton must be embedded as a contiguous block within the Bollgard II cotton field. For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the Bollgard II cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*B.t.k.* cotton may be used as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit). The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.~~

34) Embedded Refuge for Pink Bollworm Only:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton. ~~There is no field unit option.~~

Bollgard II® Cotton

Bacillus thuringiensis subsp. *kurstaki* Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production
[PV-GHBK11] in event MON 15985 cotton0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production
[PV-GHBK04] in event MON 15985 cotton0.00004 - 0.00052%*

Other Ingredients:

Substance produced by the marker genes and the genetic material necessary for their production
[PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton.....0.0022-0.0304%*

*Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

® Bollgard II is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the above listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins is planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production, and insect-resistance management.
4. Bollgard II must not be planted nor sold for commercial planting in Hawaii, Puerto Rico, U.S. Virgin Islands, south of Route 60 (near Tampa) in Florida, and in the following counties in the Texas panhandle: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of Bollgard II cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton.

MONSANTO



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

May 30, 2007

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Branch Chief
Biopesticide and Pollution Prevention Division

Subject: Submission of data matrix and product labels in support of natural refuge amendment for Bollgard II[®] cotton (EPA Reg. No. 524-522).

Dear Dr. Reilly:

On May 30, 2007, EPA sent Monsanto Company a pre-acceptance letter for a natural refuge with Bollgard II cotton (EPA Reg. No. 524-522). The purpose of this letter is to submit the updated Bollgard II cotton registration data matrix and proposed changes to the product label.

Attached are the following:

- Application for Pesticide Amendment (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Bollgard II cotton product label with highlighted changes (one copy)
- Bollgard II cotton product label (one copy)

Should you have any questions with regard to this supplemental information please contact me at 314-694-7556 or Dr. Russell Schneider at 202-383-2866.

Sincerely,

Melinda C. McCann
Cotton Regulatory Affairs Manager

cc: Mike Mendelsohn
Alan Reynolds
Russell Schneider

[®] Bollgard II is a registered trademark of Monsanto Technology LLC



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier
Number

Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 524-522	2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Bollgard II cotton	PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of data matrix in support of Bollgard II cotton registration (EPA Reg. No. 524-522).

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)		
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container		
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Dr. Russell P. Schneider		Title Regulatory Affairs Director		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature 		3. Title Regulatory Affairs Manager			
4. Typed Name Melinda C. McCann Tel. (314) 694-7556		5. Date May 30, 2007			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 (202) 383-2866

EPA Registration Number / File Symbol:

Reg. No. 524-522

Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in cotton

Date:

May 30, 2007

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:

Terrestrial field crop

Product Name:

Bollgard II cotton

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY



(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.



I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

May 30, 2007

Typed or Printed Name and Title

Melinda C. McCann, Regulatory Affairs
Manager



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.

Washington, D.C. 20460

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DATA MATRIX

Date: May 30, 2007

EPA Reg No./File Symbol: 524-522

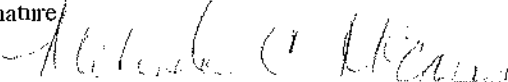
Page 1 of 23

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1400 885.1500 885.2400 885.2500	Kolwyck, D; Hamilton, K; Reed, A. (1999) GUS Protein Levels in Insect Protected Cotton Samples Produced in the U.S. Field Trials. MSL-16097. Unpublished study prepared by Monsanto Company.	44939402	Monsanto Company	OWN	Submitted 30-Sep-1999
885.1400 885.1500 885.2400 885.2500	Kolwyck, D; K Hamilton; and A Reed. (1999) Protein Levels in Insect Protected Cotton Samples Produced in the 1998 U.S. Field Trials. MSL-16612. Unpublished study prepared by Monsanto Company.	44966601	Monsanto Company	OWN	Submitted 5-Nov-1999
885.1100 885.1200 885.1500	Monsanto Company. (2000) Administrative Materials in Support of the Request for the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Corn (<i>Zea mays</i> L.) and Cotton (<i>Gossypium hirsutum</i> L.).	45086300	Monsanto Company	OWN	Submitted 4-Apr-2000
	Hamilton, K.; Reed, A. (1999) Field Report: Production of Tissue Samples from Insect Protected Cotton Events Grown in the 1998 U.S. Field Season. MSL-16019. Unpublished study prepared by Monsanto Company.	45086301	Monsanto Company	OWN	Submitted 4-Apr-2000
Signature: 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

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EPA Reg No./File Symbol: 524-522

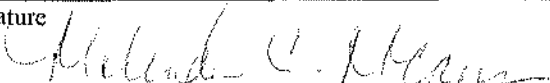
Page 2 of 23

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1300 885.2100	Doherty, S.; Hamilton, K.A.; Lirette, R.P.; Borovkova, I. (2000) Amended Report for Molecular Characterization of Cotton Event 15985. MSL-16620. Unpublished study prepared by Monsanto Company.	45086303	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4380	Maggi, V. (2000). Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Honey Bee Larvae. MSL-16175, CA-99-059, and CAR 157-99. Unpublished study prepared by California Agricultural Research.	45086307	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4380	Maggi, V. (2000) Evaluation of the Dietary Effect(s) of Insect Protection Protein 2 on Adult Honey Bees (<i>Apis mellifera</i> L.). 99-858E, CA-99-058, and CAR 156-99. Unpublished study prepared by California Agricultural Research.	45086308	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with Green Lacewing Larvae (<i>Chrysoperla cornea</i>). MSL-16171 and WL-99-061. Unpublished study prepared by Wildlife International Ltd.	45086309	Monsanto Company	OWN	Submitted 4-Apr-2000
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

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Form Approved OMB No. 2070-0060

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DATA MATRIX

Date: May 30, 2007		EPA Reg No./File Symbol: 524-522		Page 3 of 23	
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with Parasitic Hymenoptera (<i>Nasonia vitripennis</i>). MSL-16173 and WL-99-062. Unpublished study prepared by Wildlife International Ltd.	45086310	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: A Dietary Toxicity Study with the Ladybird Beetle (<i>Hippodamia convergens</i>). MSL-16172 and WL-99-060. Unpublished study prepared by Wildlife International Ltd.	45086311	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Palmer, S.; Krueger, H. (2000) Insect Protection Protein 2: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. 99-858E, 139-445, and WL-99-067. Unpublished study prepared by Wildlife International Ltd.	45086313	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4340	Teixiera, D. (2000) Assessment of Chronic Toxicity of Cotton Tissue Containing Insect Protection Protein 2 to Collembola (<i>Folsomia candida</i>): Amended Final Report. MSL-16174 and SB-99-063. Unpublished study prepared by Springborn Laboratories, Inc.	45086314	Monsanto Company	OWN	Submitted 4-Apr-2000
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4050	Gallagher, S.; Grimes, J.; Beavers, J. (2000) Insect Protection Protein 2 In Cottonseed Meal: A Dietary Toxicity Study with the Northern Bobwhite. MSL-16178. Unpublished study prepared by Wildlife International, Ltd.	45086316	Monsanto Company	OWN	Submitted 4-Apr-2000
885.4200	Li, M.; Robinson, E. (2000) Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish. MSL-16179. Unpublished study prepared by Thad Cochran National Warmwater Aquaculture Center.	45086318	Monsanto Company	OWN	Submitted 4-Apr-2000
885.5200	Dubelman, S.; Martin, J.; Bhalgat, M. (2001) Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Insect Protein 2 in Cotton Leaf Tissue. MSL-16185. Unpublished study prepared by PTRL East, Inc. and Monsanto Company.	45337101	Monsanto Company	OWN	Submitted 21-Feb-2001
885.4380	Maggi, V. (2000) Evaluation of the Dietary Effect(s) of Purified <i>Bacillus thuringiensis</i> Protein on Honey Bee Larvae. MSL-16961. Unpublished study prepared by California Agricultural Research, Inc.	45337102	Monsanto Company	OWN	Submitted 21-Feb-2001
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Date: May 30, 2007
Applicant's/Registrant's Name & Address:
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167
EPA Reg No./File Symbol: 524-522 Page 5 of 23
Product: Bollgard II cotton
Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4200	Li, M.; Robinson, E. (2001) Evaluation of Cottonseed Meal Derived from Insect Protected Cotton Lines 15813 and 15985 as a Feed Ingredient for Catfish. Amended MSL-16179. Unpublished study prepared by Thad Cochran National Warmwater Aquaculture Center.	45337103	Monsanto Company	OWN	Submitted 21-Feb-2001
885.1100 885.1200 885.1300 885.2100	Doherty, S.; Lirette, R.; Hamilton, K. (2000) Molecular Analysis of the Stability of Cotton Event 15985. MSL-16749. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 21-Feb-2001
885.2300	D. Kolwyck, K. Gustafson. Validated Method for Detection and Direct ELISA Analysis of Cry2Ab2 in Cottonseed. Unpublished study prepared by Monsanto Company.	45750201	Monsanto Company	OWN	Submitted 13-Apr-2001
885.1100 885.2200	Lee, T.C.; J.L. Lee; J.D. Astwood. (2001) Effect of Heat Treatment on the Immunodetection of Cry2Ab2, GUS, Cry1Ac and NPTII Proteins Produced in Cotton Event 15985. MSL-16810. Unpublished study prepared by Monsanto Company.	45750202	Monsanto Company	OWN	Submitted 13-Apr-2001
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G.; Reding, H. (2001) Insect Resistance Management Plan for Bollgard II Cotton. Unpublished study prepared by Monsanto Company.	45545701	Monsanto Company	OWN	Submitted 20-Nov-2001
	Burns, J.; Gustafson, K.; Reding, H. (2001) Public Interest Document for Bollgard II Cotton in Support of the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton. Unpublished study prepared by Monsanto Company.	45558801	Monsanto Company	OWN	Submitted 11-Dec-2001
858.1100 858.2200	Bannon, G.; Alibhai, M.; McCoy, R.; Reed, R.; Silvanovich, A. (2002) Safety Assessment of GUS E377K in Bollgard II cotton. MSL-17618. Unpublished study prepared by Monsanto Company.	45601801	Monsanto Company	OWN	Submitted 7-Feb-2002
885.1100 885.1200 885.1300 885.2100	Pineda, N.; Mittanck, D.; Cavato, T.; Lirette, R. (2002) PCR and DNA Sequence Analysis of the Insert in Bollgard II Cotton Event 15985. MSL-17146. Unpublished study prepared by Monsanto Company.	45601802	Monsanto Company	OWN	Submitted 7-Feb-2002
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.4340	McKee, M.; Fernandez, S. (2002) Endangered Species Impact Assessment for the Cry1Ac and Cry2Ab2 Proteins in Bollgard II Cotton. MSL-17673. Unpublished study prepared by Monsanto Company.	45608901	Monsanto Company	OWN	Submitted 18-Feb-2002
885.4340	Monsanto Company (2002) Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton (<i>Gossypium hirsutum</i> L.). EPA Reg. No 524-LEE, MRID# 45086310; Request for a waiver from the inclusion of information regarding the exposure and toxicity of the Cry2Ab2 protein to parasitic Hymenoptera (<i>Nasonia vitripennis</i>) in the ecological risk assessment.	No MRID assigned	Monsanto Company	OWN	Submitted 18-Apr-2002
	Monsanto Company (2002) Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab Insect Control Protein, as Produced in Cotton (<i>Gossypium hirsutum</i> L.). EPA File Symbol: 524-LEE.	No MRID assigned	Monsanto Company	OWN	Submitted 7-Jun-2002
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2002) Request for Clarification of Conditions of Registration of the Plant-Incorporated Protectant, Cry2Ab2 Insect Control Protein in cotton.	No MRID assigned	Monsanto Company	OWN	Submitted 17-July-2002
885.1100 885.1200 885.1500	Monsanto Company (2002) Administrative Materials for Application to Amend the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 Insect Control Protein, from Seed Increase/Plant Propagation to Full Commercial Use for Cotton. 99-CT-858E.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
	Monsanto Company (2002) Responses to EPA questions regarding the Insect Resistance management (IRM) plan for Bollgard II cotton, in support of the registration request for the plant-incorporated protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 insect control protein, as expressed in cotton, EPA Reg. No. 524-522.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1500	Monsanto Company. (2002) Administrative Materials for Application to Amend the Registration of the Plant-Incorporated Protectant, <i>Bacillus thuringiensis</i> Cry2Ab2 Insect Control Protein from a Seed Increase/Plant Propagation approval to Full Commercial Use for Cotton; EPA Reg. No. 524-522.	No MRID assigned	Monsanto Company	OWN	Submitted 16-Aug-2002
885.5200	Dubelman, S.; Ayden, B.; Mueth, M.; Jiang, C.; Brown, C.; Uffman, J.; Duan, J. (2002) Aerobic Soil Degradation of the <i>Bacillus thuringiensis</i> Cry2Ab2 Protein Derived from Cotton Leaf Tissue. MSL-16892. Unpublished study prepared by Monsanto Company.	45806601	Monsanto Company	OWN	Submitted 22-Nov-2002
	Shappley, Z.; Lahman, L. (2002) An Analysis of the Outcrossing Potential of Upland Cotton (<i>Gossypium hirsutum</i> L.) Sprayed with Insecticides Within Field Plots in Northwestern Puerto Rico. MSL-18716. Unpublished study prepared by Monsanto Company.	46008002	Monsanto Company	OWN	Submitted 04-Jun-2003
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Lahman, L. (2003) Segregation Data from the Cottonseed Used in the Analysis of the Outcrossing Potential of Upland Cotton (<i>Gossypium hirsutum</i> L.) Sprayed with Insecticides within Field Plots in Northwestern Puerto Rico. 99-CT-858E. Unpublished study prepared by Monsanto Company.	46098101	Monsanto Company	OWN	Submitted 17-Oct-2003
885.2300	Brown, M. (2003) Independent Lab Validation of the Strategic Diagnostics Inc. Seed Cry2Ab Lateral Flow Test Strip Performance Verification for Cottonseed. Unpublished study prepared by Strategic Diagnostics, Inc.	46155401	Monsanto Company	OWN	Submitted 19-Dec-2003
885.2300	Brown, M. (2003) Characterization of Antibody Used in Strategic Diagnostics Inc. Seed Cry2Ab Lateral Flow Strip Test. Unpublished study prepared by Strategic Diagnostics, Inc.	46155402	Monsanto Company	OWN	Submitted 19-Dec-2003
885.5200	Dubelman, S.; Mueth, M.; Jiang, C.; Jiang, C.; Brown, C. (2003) Determination of Soil Concentrations of Cry1Ac and Cry2Ab2 Proteins in Field Plots Planted with Bollgard and Bollgard II Cotton. MSL-17248. Unpublished study prepared by Monsanto Company and Agvise Inc.	46179001	Monsanto Company	OWN	Submitted 21-Jan-2004
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Starke, M. (2004) Monsanto Bollgard and Bollgard II Cotton Seed Units Sold in the U.S. in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 29-Jan-2004
	DiNicola, N.; Starke, M. (2004) 2003 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. Unpublished study prepared by Monsanto Company.	46184401	Monsanto Company	OWN	Submitted 30-Jan-2004
885.1400 885.1500 885.2400 885.2500	Mozaffar, S.; Sayegh, F.; Lirette, R. (2003) Cry2Ab2 Protein Levels in Tissues Collected from Bollgard II Cotton Produced in U.S. Field Trials. MSL-18666. Unpublished study prepared by Monsanto Company.	46222301	Monsanto Company	OWN	Submitted 12-Mar-2004
	Head, G.; Voth, R. (2004) A Final Report on Studies to Assess Production of <i>Helicoverpa zea</i> from Alternate Host Plants and from the External Unsprayed Non-Bt Cotton Refuge for Bollgard Cotton. MSL-19238. Unpublished study prepared by Monsanto Company.	46222401	Monsanto Company	OWN	Submitted 15-Mar-2004
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Greenplate, J. (2004) Report on Studies to Assess Supplemental Pyrethroid Spray Effects on <i>Helicoverpa zea</i> Populations in Bollgard Cotton. MSL-19252. Unpublished study prepared by Monsanto Company.	46222402	Monsanto Company	OWN	Submitted 15-Mar-2004
	Gustafson, D.; Head, G.; Reding, K. (2001) Impact of Effective Refuge Size and Typical Insecticide Use Practices on Model Predictions of Years to Resistance of Tobacco Budworm and Cotton Bollworm to Bollgard Cotton. MSL-19229. Unpublished study prepared by Monsanto Company.	46222403	Monsanto Company	OWN	Submitted 15-Mar-2004
	Gould, F.; Blair, N.; Reid, M.; Rennie, T.; Lopez, J.; Micinski, J. (2002) <i>Bacillus thuringiensis</i> - Toxin Resistance Management: Stable Isotope Assessment of Alternate Host Use by <i>Helicoverpa zea</i> . PNAS 2002 99: 16581-16586.	46242501	Monsanto Company	PL	Submitted 15-Mar-2004
	Agricultural Biotechnology Stewardship Technical Committee (2004) Extent of Corn Earworm (<i>Helicoverpa zea</i>) North-South Migration and Impact on Resistance Management for Bt Crops. Unpublished study prepared by Agricultural Biotechnology Stewardship Technical Committee.	46242502	Monsanto Company	OWN	Submitted 15-Mar-2004
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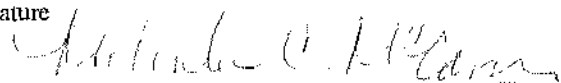
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Unnithan, G.; Brink, S.; Wood, B.; et al. (2004) Susceptibility of Southwestern Pink Bollworm to Cry2Ab2: Baseline responses in 2001 and 2002. Project Number: 99-CT-858E. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46272001	Monsanto Company	OWN	Submitted 13-May-2004
	Ali, I.; Luttrell, R. (2004) Baseline Susceptibility of <i>Heliothis virescens</i> and <i>Helicoverpa zea</i> to Cry2Ab2. 99-CT-858E. Unpublished study prepared by University of Arkansas.	46272002	Monsanto Company	OWN	Submitted 13-May-2004
	Blanco, C.; Mullen, M. (2004) <i>Bacillus thuringiensis</i> Resistance Monitoring Program for Tobacco Budworm and Bollworm in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by USDA-ARS-SIMRU.	46272003	Monsanto Company	OWN	Submitted 13-May-2004
	Monsanto Company (2004) Submission of a Bollgard II cotton remedial action plan for tobacco budworm and cotton bollworm as of condition of registration (EPA Reg. No 524-522). 99-CT-858E.	No MRID assigned	Monsanto Company	OWN	Submitted 29-Jan-2004
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Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton			
Ingredient <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Bhatti, M.; Lahman, L.; Shapiro, J.; et al.; (2004) Monitoring the Effectiveness of Insecticidal Sprays to Limit Outcrossing from Bollgard II Cotton to the Conventional Cotton Planted in Border Rows in a 2003-2004 Puerto Rico Cotton Breeding Nursery: Final Report. MSL-19341 and 99-CT-858E. Unpublished study prepared by Monsanto Company.	46308801	Monsanto Company	OWN	Submitted 29-Jun-2004
	Lahman, L.K. (2004) Supplemental Sales and Acreage Data for Bollgard and Bollgard II Cotton in 2003. 94-041E, 00-CT-006E, and 99-CT-858E. Unpublished study prepared by Monsanto Company.	No MRID assigned	Monsanto Company	OWN	Submitted 8-Oct-2004
	Monsanto Company. (2004) Response to August 25, 2004 EPA letter regarding Insect Resistance Monitoring, the Compliance Assurance Program Community refuge Program, Grower Education, Remedial Action and Sales Data for the Bollgard and Bollgard II registrations.	No MRID assigned	Monsanto Company	OWN	Submitted 8-Oct-2004
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.		Date May 30, 2007

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DATA MATRIX

Date: May 30, 2007

EPA Reg No./File Symbol: 524-522


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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company. (2004) Submission of the revised remedial action plans for tobacco budworm and cotton bollworm required as conditions of the Bollgard and Bollgard II cotton registrations. 04-CT-133E-2 and 04-CT-134E-2.	No MRID assigned	Monsanto Company	OWN	Submitted 12-Nov-2004
	Dennehy, T.; Unnithan, G.; Brink, S.; et al. (2004) Susceptibility of Southwestern Pink Bollworm to Bt toxins CryIAc and Cry2Ab2: Final Results of 2003 Season. 04-CT-133E-2 and 04-CT-134E-2. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46441901	Monsanto Company	OWN	Submitted 20-Dec-2004
	Pester, T.; Starke, M.; DiNicola, N. (2005) The 2004 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E-6 and 04-CT-134E-6. Unpublished study prepared by Monsanto Company.	46457101	Monsanto Company	OWN	Submitted 28-Jan-2005
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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Date: May 30, 2007

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Pester, T.; Starke, M. (2005) The 2004 Bollgard and Bollgard II Cotton Community Refuge Program Survey Report and Community Refuge Agreement Forms. 04-CT-133E-7 and 04-CT-134E-7. Unpublished study prepared by Monsanto Company.	46482801	Monsanto Company	OWN	Submitted 28-Jan-2005
	Starke, M. (2005) Monsanto Bollgard II Cotton Seed Units Sold and Estimate of Acres Planted in the U.S. in 2004. 04-CT-134E-4. Unpublished study prepared by Monsanto Company.	46483401	Monsanto Company	OWN	Submitted 28-Jan-2005
	Blanco, C. (2005) <i>Bacillus thuringiensis</i> Cry1Ac/Cry2Ab2 Resistance Monitoring Program for Tobacco Budworm and Bollworm in 2004. 04-CT-133E-11 and 04-CT-134-11. Unpublished study prepared by USDA-ARS-SIMRU.	46547601	Monsanto Company	OWN	Submitted 13-May-2005
	Ali, I.; Luttrell, R. (2005) Baseline Susceptibility of <i>Heliothis virescens</i> to Cry2Ab2: Final Report. 04-CT-133E-11. Unpublished study prepared by University of Arkansas.	46547602	Monsanto Company	OWN	Submitted 13-May-2005
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
885.1100 885.1200 885.1500	Monsanto Company (2005) Submission of revised Confidential Statement of Formula (CSF) and final printed labels for Bollgard II cotton (EPA Reg. No. 524-522). 04-CT-133E-13.	No MRID assigned	Monsanto Company	OWN	Submitted 3-Oct-2005
	Monsanto Company (2005) Request to Amend the Conditions of Registration for Bollgard II cotton. 04-CT-133E-15.	No MRID assigned	Monsanto Company	OWN	Submitted 15-Nov-2005
885.1400 885.2250	Head, G.; Gustafson, D. (2005) Production of Tobacco Budworm from Alternative Host Plants and the Role of These Host Plants as Natural Refuge for Bollgard II Cotton. 04-CT-113E-17, 04-01-36-04, and MSL-20123. Unpublished study prepared by Monsanto Company.	46717201	Monsanto Company	OWN	Submitted 20-Dec-2005
	Gustafson, D.; Head, G. (2005) Modeling the Impact of Natural Refuge on the Evolution of Tobacco Budworm and Cotton Bollworm Resistance to Bollgard II Cotton. 04-CT-133E-17 and MSL-19689. Unpublished study prepared by Monsanto Company.	46717202	Monsanto Company	OWN	Submitted 20-Dec-2005
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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Applicant's/Registrant's Name & Address:
Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167
Product: Bollgard II cotton
Ingredient *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G.; McCann, M.; Mullins, J. (2005) Scientific and Economic Justification for Not Requiring Structured Cotton Refuges for Bollgard II Cotton in the U.S. Cotton Belt from Texas to the East Coast. 04-CT-133E-17 and MSL-2009I. Unpublished study prepared by Monsanto Company.	46717203	Monsanto Company	OWN	Submitted 20-Dec-2005
	Dennehy, T.; Unnithan, G.; Brink, S.; et al. (2005) Susceptibility to Bt Toxins CryI Ac and Cry2Ab2 of Southwestern Pink Bollworm in 2004. 04-CT-133E-16 and 04-CT-134E-16. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	46735001	Monsanto Company	OWN	Submitted 20-Dec-2005
	Bookout, J. (2006) 2005 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E-21 and 04-CT-134E-21. Unpublished study prepared by Monsanto Company.	46745501	Monsanto Company	OWN	Submitted 27-Jan-2006
	McCann, M.; Whittle, M. (2006) 2005 Bollgard and Bollgard II Cotton Community Refuge Program Report. 04-CT-133E-18 and 04-CT-134E-18. Unpublished study prepared by Monsanto Company.	46754701	Monsanto Company	OWN	Submitted 27-Jan-2006
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	



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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	McCann, M.; Whittle, M. (2006) Bollgard II Cotton Seed Units Sold in the U.S. in 2005. 04-CT-133E-19. Unpublished study prepared by Monsanto Company.	46754801	Monsanto Company	OWN	Submitted 27-Jan-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 3-Apr-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 7-Apr-2006
	Monsanto Company (2006) Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted December 21, 2005 (EPA Reg. No. 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 10-May-2006
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Blanco, C. (2006) <i>Bacillus thuringiensis</i> Cry1Ac and Cry2Ab2 Resistance Monitoring Program in Field-Collected Tobacco Budworm and Bollworm in 2005 - Annual Report. 04-CT-133E-22 and 04-CT-134E-22. Unpublished study prepared by Monsanto Company.	46826601	Monsanto Company	OWN	Submitted 10-May-2006
	Ali, I.; Luttrell, R. (2006) Susceptibles of <i>Heliothis virescens</i> and <i>Helicoverpa zea</i> to Cry2Ab2 Insecticidal Protein in Diet Incorporated Assays Conducted in 2005. 04-CT-133E-22 and 04-CT-134E-22. Unpublished study prepared by University of Arkansas.	46826602	Monsanto Company	OWN	Submitted 10-May-2006
885.1400 885.2250	Head, G. (2006) Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts for Monsanto's Bollgard II Cotton. 06-RA-36-02 and 04-CT-133E-12. Unpublished study prepared by Monsanto Company.	46982001	Monsanto Company	OWN	Submitted 10-Nov-2006
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Dennehy, T.; Unnithan, G.; Harpold, V.; et al. (2006) Susceptibility of Southwestern Pink Bollworm to Bt Toxins Cry1Ac and Cry2Ab2 in 2005: Bollgard and Bollgard II Cotton. 04-CT-133E-26 and 04-CT-134E-26. Unpublished study prepared by University of Arizona and Arizona Cotton Research and Protection Council.	47021601	Monsanto Company	OWN	Submitted 15-Dec-2006
	McCann, M.C. and Carden, J.A. (2007) Bollgard II Cotton Seed Units Sold in the U.S. in 2006. 04-CT-133E-28. Unpublished study prepared by Monsanto Company.	47042801	Monsanto Company	OWN	Submitted 29-Jan-2007
	Reding, K.; Carden, J. (2007) 2006 Bollgard and Bollgard II Cotton Insect Resistance Management Compliance Assurance Program Report. 04-CT-133E and 04-CT-134E. Unpublished study prepared by Monsanto Company.	47042701	Monsanto Company	OWN	Submitted 29-Jan-2007
885.2250	Head, G.; Orth, R. (2007) Independent Laboratory Validation and Publication of Gossypol Determination Method for Adult Lepidoptera. 04-CT-133E-29. Unpublished study prepared by Covance Laboratories, Inc.	47059101	Monsanto Company	OWN	Submitted 14-Feb-2007
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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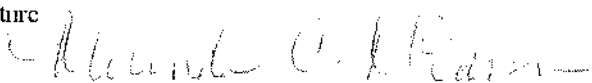
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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient: *Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Monsanto Company (2007) Follow up from EPA BPPD and Monsanto Company meeting regarding the planting restriction in Texas for Bollgard and Bollgard II cotton (EPA Reg. Nos. 524-478 and 524-522).	47101000	Monsanto Company	OWN	Submitted 6-Apr-2007
	McCann, M. (2007) Bollgard and Bollgard II Cotton Seed Units Sold in 10 Texas Counties from 1998 to 2006. 04-CT-133E-30 and 04-CT-134E-30. Unpublished study prepared by Monsanto Company.	47101001	Monsanto Company	OWN	Submitted 6-Apr-2007
	Head, G. (2007) Determination of No Harm from Bollgard and Bollgard II Cotton Plantings in 10 Restricted Texas Counties. 04-CT-133E-30 and 04-CT-134E-30. Unpublished study prepared by Monsanto Company.	47101002	Monsanto Company	OWN	Submitted 6-Apr-2007
	Monsanto Company (2007) Information requested by EPA BPPD in support of the registrations for Bollgard and Bollgard II cotton (EPA Reg. Nos. 524-478 and 524-522).	No MRID assigned	Monsanto Company	OWN	Submitted 17-Apr-2007
Signature 			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date May 30, 2007	

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Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G.P. and Gustafson, D.I. (2007) Monsanto's Response to U.S. EPA Questions on Natural Refuge Modeling and Statistical Analysis. 04-CT-133E-20. Unpublished study prepared by Monsanto Company.	Not assigned yet	Monsanto Company	OWN	Submitted 16-May-2007

Signature

Name and Title

Melinda C. McCann
Regulatory Affairs Mgr.

Date

May 30, 2007



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY 30 2007

Dr. Russell P. Schneider
Regulatory Affairs Director
Monsanto Company
1300 I Street, NW, Suite 450 East
Washington, DC 20005

Dear Dr. Schneider:

Subject: Pre-Acceptance Letter Regarding Your November 10, 2006 Amendment Application to
Change the Refuge Requirements
EPA Registration No. 524-522

This is a pre-acceptance letter regarding Monsanto Company's application to amend the above referenced product for a Section 3 amendment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider amending Monsanto Company's Bollgard II Cotton product under FIFRA Section 3(c)(5) provided Monsanto Company amends its amendment application by submitting the required information as described in this letter.

This letter does not constitute a commitment to amend the subject product, nor is it intended to imply that EPA will amend the subject product. Rather, the purpose of this letter is to inform you that, if Monsanto Company submits the information in writing as described in this letter, EPA will be able to continue to process the amendment application in accordance with our normal procedures.

Thus, to enable us to continue to process the subject registration application, EPA requests that the Monsanto Company agree in writing to the following.

- 1) Submit a revised label, updated data matrix, and Certification with Respect to Citation of Data form.
- 2) Terms and conditions numbers 3-5 of the September 27, 2006 Notice of Registration will be amended as follows:

- 3) This is an amended registration pursuant to FIFRA Section 3(c)(5) and is unconditional.

The following information regarding commercial production must be included in the grower guide for Bollgard II® cotton and is a term of this registration:

- a) No planting or sale for commercial planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) No planting or sale for commercial planting of Bollgard II cotton is permitted in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

c) No planting or sale for commercial planting of Bollgard II cotton is permitted in the following counties in the Texas panhandle: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton intended for these purposes and is a term of this amendment:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

4. Insect Resistance Management Program Elements. The required IRM program for Bollgard II cotton must have the following elements:

- a. Requirements for a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- b. Requirements for Monsanto to prepare and require Bollgard II cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the IRM requirements;
- c. Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- d. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
- e. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1Ac and Cry2Ab2 proteins in the target insects;
- f. Requirements for Monsanto to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- g. Requirements for annual reports on or before January 31st each year for compliance assurance (including grower education) and sales. The tobacco budworm and cotton bollworm annual resistance monitoring reports must be submitted to EPA on or before June 30th each year and for pink bollworm, the annual resistance monitoring report must be submitted to EPA on or before December 31st each year. See Annual Reports section below.

5. Insect Resistance Management Requirements

- a. Refuge Requirements for Pink Bollworm Resistance Management only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.

All growers of Bollgard II® cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of Bollgard II® cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Btk* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* cotton refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard II cotton.

- b. Natural Refuge Requirements for Tobacco Budworm and Cotton Bollworm Resistance Management only in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky,

Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas (excluding the following counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler), and Virginia.

- 1) Tobacco budworm sampling must be conducted for at least one year in west Texas, Alabama, and Tennessee. An appropriate gossypol analysis, statistical analysis, calculation of effective and natural refuge, and simulation modeling must be performed to determine the likelihood of tobacco budworm resistance to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II® cotton using natural refuge. Previously, these states had only a single year of sampling data and analysis to support the natural refuge. The new data collected in 2007 and/or 2008 must be compared with previously collected data (2004 to 2006, depending on the location) to confirm the effectiveness of a natural refuge. A report of these findings must be submitted to EPA on or before January 31st following the year of collection.
- 2) Monsanto must submit data to EPA by January 31st, 2012, and every five years thereafter, to support an EPA reassessment of the natural refuge and to confirm its effectiveness with tobacco budworm and cotton bollworm. The data must include: resistance monitoring data, cropping pattern analysis, and simulation modeling to reexamine levels of effective refuge in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Both cropping and land use patterns can change over time, which could impact the amount of natural refuge available to tobacco budworm and cotton bollworm relative to cotton. If based on this reassessment, EPA determines that additional tobacco budworm and/or cotton bollworm sampling, gossypol analysis, statistical analysis, and simulation modeling are needed to justify continuation of the natural refuge, Monsanto must submit these data within the EPA requested timeframe. If EPA's assessment concludes that the natural refuge is no longer scientifically supported, Monsanto agrees to submit an application to amend the registration to restore the structured refuge requirements previously required for tobacco budworm and cotton bollworm uses.
- 3) It is recommended that Monsanto develop a more complex, spatial model of resistance for Bollgard II cotton that further considers the evolution of resistance "hotspots" (i.e. localized areas of resistance) and provide EPA with this information. Key issues like spatial structure, linkage disequilibrium, and differential movement of males and females have not yet been explored in detail for pyramided Bt proteins. Such models would be more desirable to examine the resistance evolution at the local level where natural refuge may be limited for one or more generations of tobacco budworm.

c. Grower Agreements

While Monsanto will have flexibility to design its program to fit its own business practices, the registration is specifically conditioned on meeting the following requirements.

- 1) Persons purchasing the Bollgard II cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM

program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must continue to implement an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use an approved grower agreement. If Monsanto wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this amendment.

5) Monsanto must continue an approved system which is reasonably likely to assure that persons purchasing the Bollgard II cotton sign grower agreement(s).

6) Monsanto shall maintain records of all Bollgard II cotton grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of the Bollgard II cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior October through September.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

d. IRM Education and IRM Compliance Monitoring Programs

Monsanto must implement the following IRM education and compliance monitoring programs:

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bollgard II cotton users the importance of complying with the IRM program. The program shall include information encouraging Bollgard II cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bollgard II cotton

fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each Bollgard II® cotton grower separate from the grower agreement. Monsanto shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Annually, Monsanto shall provide a report to EPA any substantive changes to the grower education activities as a part of the overall IRM compliance assurance program report.

4) Monsanto shall continue to implement an ongoing, approved IRM compliance assurance program in the states of Arizona, California, and New Mexico and in the following Texas Counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. The program is designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Bollgard II® cotton product. Other required features of the program are described in paragraphs 5 - 12 below.

5) Monsanto shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bollgard II cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bollgard II cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year.

Monsanto shall confer with EPA on the design and content of the survey prior to its implementation.

7) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto will confer with the Agency prior to adopting any changes.

8) Monsanto must conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with Bollgard II® cotton growers to perform assessments of compliance with IRM requirements. There is no minimum cotton acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

9) Monsanto shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

10) If a grower, who purchases Bollgard II cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

11) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto, the number of tips investigated, the percent of growers who were not complying with the IRM requirements, and the follow-up actions taken.

12) Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

e. Insect Resistance Monitoring.

Monsanto must conduct an annual resistance monitoring program for *Heliothis virescens* (tobacco budworm) *Helicoverpa zea* (cotton bollworm), and *Gossypiella pectinophora* (pink bollworm) for the Cry1Ac and Cry2Ab2 toxins expressed in Bollgard II cotton as early as possible. Resistance monitoring programs must include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following terms and conditions:

- 1) Monsanto must submit a revised Bollgard II cotton (Cry2Ab2 and Cry1Ac toxins) resistance monitoring plan for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm) to EPA by September 1, 2007. A revised resistance monitoring plan approved by EPA must be used beginning in the 2008 growing season. The monitoring program must include increased sampling for tobacco budworm and cotton bollworm in the areas that have the greatest variability and potentially lowest levels of effective natural refuge. Sampling efforts should include all of the “worst-case” counties identified in Monsanto’s 2004 to 2006 analyses of natural refuge in the states of Texas, Tennessee, Mississippi, Louisiana, Arkansas, Alabama, Georgia, and North Carolina. BPPD believes that resistance monitoring for tobacco budworm and cotton bollworm resistance to Cry1Ac and Cry2Ab2 will have added importance with adoption of a natural refuge as a resistance management strategy.
- 2) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest.
- 3) The following testing scheme for survivors of the diagnostic or discriminating concentrations (or identified survivors of any resistance detection method) must be implemented: 1) Determine if the observed effect is heritable; 2) Determine if the increased tolerance can be observed in the field (i.e., survive on Bollgard II® cotton plants); 3) Determine if the effect is due to resistance, 4) Determine the nature of resistance (dominant, recessive), 5) Determine the resistance allele frequency, 6) Determine, in subsequent years, whether the resistance allele frequency is increasing, and 7) Determine the geographic extent of the resistance allele (or alleles) distribution. Should the resistance allele frequency be increasing and spreading, a specific remedial action plan should be designed to mitigate the extent of Bt resistance. See section e. (“Remedial Action Plans”) below.

- 4) Monsanto must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, cotton leafperforator and European corn borer. Monsanto will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto will investigate all damage reports. See Remedial Action Plans section below.
- 5) Monsanto must provide to EPA for review and approval any revisions to the tobacco budworm, cotton bollworm, and pink bollworm resistance monitoring plans prior to their implementation.
- 6) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

f. Remedial Action Plans

Specific remedial action plans are required for Bollgard II® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto must implement the Arizona *Bt* Cotton Working Group's Remedial Action Plan. Monsanto must obtain approval from EPA before modifying the Arizona *Bt* Cotton Working Group's Remedial Action Strategy. 2) Remedial (Mitigation)

Action Plan for Tobacco Budworm and Cotton Bollworm

If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto must implement the Remedial Action Plan approved by EPA. Monsanto must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

g. Annual Reports for Sales, Grower Education, Compliance Assurance, Grower Agreements, and Resistance Monitoring.

Annually by January 31st, Monsanto will provide EPA a report that contains the following information: number of units of the Bollgard II® cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements, results of the compliance assurance program including any substantive changes to the grower education program, and a sales report. The annual sales report should contain a summary of all Bollgard II cotton sales summarized by state (county level information available upon request) except for the ten restricted counties in Texas; in those counties, Monsanto must provide county-level sales information.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

This letter does not mean that EPA agrees to amend the subject product. If Monsanto submits the information in writing as described in this letter, however, EPA will be able to continue to process the registration application.

Sincerely,

A handwritten signature in black ink, appearing to read 'Sheryl Reilly', is positioned above the typed name and title.

Sheryl Reilly, Ph.D. Chief
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 30 2007

Dr. Russell P. Schneider
Regulatory Affairs Director
Monsanto Company
1300 I Street, NW, Suite 450 East
Washington, DC 20005

Dear Dr. Schneider:

Subject: Pre-Acceptance Letter Regarding Your November 10, 2006 Amendment Application to
Change the Refuge Requirements
EPA Registration No. 524-522

This is a pre-acceptance letter regarding Monsanto Company's application to amend the above referenced product for a Section 3 amendment under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Environmental Protection Agency (EPA) will consider amending Monsanto Company's Bollgard II Cotton product under FIFRA Section 3(c)(5) provided Monsanto Company amends its amendment application by submitting the required information as described in this letter.

This letter does not constitute a commitment to amend the subject product, nor is it intended to imply that EPA will amend the subject product. Rather, the purpose of this letter is to inform you that, if Monsanto Company submits the information in writing as described in this letter, EPA will be able to continue to process the amendment application in accordance with our normal procedures.

Thus, to enable us to continue to process the subject registration application, EPA requests that the Monsanto Company agree in writing to the following.

- 1) Submit a revised label, updated data matrix, and Certification with Respect to Citation of Data form.
- 2) Terms and conditions numbers 3-5 of the September 27, 2006 Notice of Registration will be amended as follows:
- 3) This is an amended registration pursuant to FIFRA Section 3(c)(5) and is unconditional.

The following information regarding commercial production must be included in the grower guide for Bollgard II® cotton and is a term of this registration:

CONCURRENCES						
SYMBOL	a) No planting or sale for commercial planting of Bollgard II cotton is permitted south of					
SURNAME	Route 60 (near Tampa) in Florida.					
DATE	b) No planting or sale for commercial planting of Bollgard II cotton is permitted in					
	Hawaii, Puerto Rico, and the U.S. Virgin Islands.					

c) No planting or sale for commercial planting of Bollgard II cotton is permitted in the following counties in the Texas panhandle: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton intended for these purposes and is a term of this amendment:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

4. Insect Resistance Management Program Elements. The required IRM program for Bollgard II cotton must have the following elements:
- a. Requirements for a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II cotton in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
 - b. Requirements for Monsanto to prepare and require Bollgard II cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the IRM requirements;
 - c. Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
 - d. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler;
 - e. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1Ac and Cry2Ab2 proteins in the target insects;
 - f. Requirements for Monsanto to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
 - g. Requirements for annual reports on or before January 31st each year for compliance assurance (including grower education) and sales. The tobacco budworm and cotton bollworm annual resistance monitoring reports must be submitted to EPA on or before June 30th each year and for pink bollworm, the annual resistance monitoring report must be submitted to EPA on or before December 31st each year. See Annual Reports section below.

5. Insect Resistance Management Requirements

- a. Refuge Requirements for Pink Bollworm Resistance Management only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.

All growers of Bollgard II® cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of Bollgard II® cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Btk* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* cotton refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard II cotton.

CONCURRENCES							
SYMBOL							15110
SURNAME	b. Natural Refuge Requirements for Tobacco Budworm and Cotton Bollworm Resistance Management only in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky,						
DATE	5/30/07						

Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas (excluding the following counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler), and Virginia.

- 1) Tobacco budworm sampling must be conducted for at least one year in west Texas, Alabama, and Tennessee. An appropriate gossypol analysis, statistical analysis, calculation of effective and natural refuge, and simulation modeling must be performed to determine the likelihood of tobacco budworm resistance to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II® cotton using natural refuge. Previously, these states had only a single year of sampling data and analysis to support the natural refuge. The new data collected in 2007 and/or 2008 must be compared with previously collected data (2004 to 2006, depending on the location) to confirm the effectiveness of a natural refuge. A report of these findings must be submitted to EPA on or before January 31st following the year of collection.
- 2) Monsanto must submit data to EPA by January 31st, 2012, and every five years thereafter, to support an EPA reassessment of the natural refuge and to confirm its effectiveness with tobacco budworm and cotton bollworm. The data must include: resistance monitoring data, cropping pattern analysis, and simulation modeling to reexamine levels of effective refuge in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia. Both cropping and land use patterns can change over time, which could impact the amount of natural refuge available to tobacco budworm and cotton bollworm relative to cotton. If based on this reassessment, EPA determines that additional tobacco budworm and/or cotton bollworm sampling, gossypol analysis, statistical analysis, and simulation modeling are needed to justify continuation of the natural refuge, Monsanto must submit these data within the EPA requested timeframe. If EPA's assessment concludes that the natural refuge is no longer scientifically supported, Monsanto agrees to submit an application to amend the registration to restore the structured refuge requirements previously required for tobacco budworm and cotton bollworm uses.
- 3) It is recommended that Monsanto develop a more complex, spatial model of resistance for Bollgard II cotton that further considers the evolution of resistance "hotspots" (i.e. localized areas of resistance) and provide EPA with this information. Key issues like spatial structure, linkage disequilibrium, and differential movement of males and females have not yet been explored in detail for pyramided Bt proteins. Such models would be more desirable to examine the resistance evolution at the local level where natural refuge may be limited for one or more generations of tobacco budworm.

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- 2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM

program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must continue to implement an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use an approved grower agreement. If Monsanto wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this amendment.

5) Monsanto must continue an approved system which is reasonably likely to assure that persons purchasing the Bollgard II cotton sign grower agreement(s).

6) Monsanto shall maintain records of all Bollgard II cotton grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of the Bollgard II cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior October through September.

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SYMBOL								
SURNAME				5				
DATE								

fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each Bollgard II® cotton grower separate from the grower agreement. Monsanto shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.

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5) Monsanto shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bollgard II cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bollgard II cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year.

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7) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto will confer with the Agency prior to adopting any changes.

8) Monsanto must conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with Bollgard II® cotton growers to perform assessments of compliance with IRM requirements. There is no minimum cotton acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

9) Monsanto shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

10) If a grower, who purchases Bollgard II cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

11) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto, the number of tips investigated, the percent of growers who were not complying with the IRM requirements, and the follow-up actions taken.

12) Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

e. Insect Resistance Monitoring CONCURRENCES

SYMBOL ▶								
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DATE ▶								

Monsanto must conduct an annual resistance monitoring program for *Heliothis virescens* (tobacco budworm) *Helicoverpa zea* (cotton bollworm), and *Gossypiella pectinophora* (pink bollworm) for the Cry1Ac and Cry2Ab2 toxins expressed in Bollgard II cotton as early as possible. Resistance monitoring programs must include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following terms and conditions:

- 1) Monsanto must submit a revised Bollgard II cotton (Cry2Ab2 and Cry1Ac toxins) resistance monitoring plan for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm) to EPA by September 1, 2007. A revised resistance monitoring plan approved by EPA must be used beginning in the 2008 growing season. The monitoring program must include increased sampling for tobacco budworm and cotton bollworm in the areas that have the greatest variability and potentially lowest levels of effective natural refuge. Sampling efforts should include all of the "worst-case" counties identified in Monsanto's 2004 to 2006 analyses of natural refuge in the states of Texas, Tennessee, Mississippi, Louisiana, Arkansas, Alabama, Georgia, and North Carolina. BPPD believes that resistance monitoring for tobacco budworm and cotton bollworm resistance to Cry1Ac and Cry2Ab2 will have added importance with adoption of a natural refuge as a resistance management strategy.
- 2) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest.
- 3) The following testing scheme for survivors of the diagnostic or discriminating concentrations (or identified survivors of any resistance detection method) must be implemented: 1) Determine if the observed effect is heritable; 2) Determine if the increased tolerance can be observed in the field (i.e., survive on Bollgard II® cotton plants); 3) Determine if the effect is due to resistance, 4) Determine the nature of resistance (dominant, recessive), 5) Determine the resistance allele frequency, 6) Determine, in subsequent years, whether the resistance allele frequency is increasing, and 7) Determine the geographic extent of the resistance allele (or alleles) distribution. Should the resistance allele frequency be increasing and spreading, a specific remedial action plan should be designed to mitigate the extent of Bt resistance. See section e. ("Remedial Action Plans") below.

- 4) Monsanto must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, cotton leafperforator and European corn borer. Monsanto will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto will investigate all damage reports. See Remedial Action Plans section below.
- 5) Monsanto must provide to EPA for review and approval any revisions to the tobacco budworm, cotton bollworm, and pink bollworm resistance monitoring plans prior to their implementation.
- 6) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

f. Remedial Action Plans

Specific remedial action plans are required for Bollgard II® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto must implement the Arizona Bt Cotton Working Group's Remedial Action Plan. Monsanto must obtain approval from EPA before modifying the Arizona Bt Cotton Working Group's Remedial Action Strategy.

2) Remedial (Mitigation) Action Plan for Tobacco Budworm and Cotton Bollworm

If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto must implement the Remedial Action Plan approved by EPA. Monsanto must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

g. Annual Reports for Sales, Grower Education, Compliance Assurance, Grower Agreements, and Resistance Monitoring.

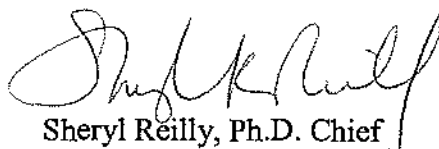
SYMBOL								
SURNAME								
DATE								

Annually by January 31st, Monsanto will provide EPA a report that contains the following information: number of units of the Bollgard II® cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements, results of the compliance assurance program including any substantive changes to the grower education program, and a sales report. The annual sales report should contain a summary of all Bollgard II cotton sales summarized by state (county level information available upon request) except for the ten restricted counties in Texas; in those counties, Monsanto must provide county-level sales information.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

This letter does not mean that EPA agrees to amend the subject product. If Monsanto submits the information in writing as described in this letter, however, EPA will be able to continue to process the registration application.

Sincerely,

A handwritten signature in dark ink, appearing to read 'Sheryl Reilly', is positioned above the printed name and title.

Sheryl Reilly, Ph.D. Chief
Microbial Pesticide Branch
Biopesticides and Pollution
Prevention Division (7511P)

Janet
Andersen/DC/USEPA/US
05/30/2007 06:49 AM

To Sharlene Matter/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA, Sheryl

cc

bcc

Subject Re: Fw: Final BGII terms 

Great. This looks like a go! Good work by everyone. You have really done a thoughtful job and let the science be the driver. This was good professional team work!

Sharlene
Matten/DC/USEPA/US
05/29/2007 04:24 PM

To Mike Mendelsohn/DC/USEPA/US@EPA
cc Janet Andersen/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA
bcc
Subject Re: Fw: Final BGII terms

Mike --

I concur with what Monsanto has provided in their mark-up.

I have checked all of the Texas counties Monsanto has identified as either 1) 10 restricted counties in the TX panhandle or 2) 15 counties in which have ongoing pink bollworm resistance management using suppression/eradication methods but with structured refuge requirements. I have provided you with a highlighted map of Texas with these counties clearly identified (on your chair). Here is the webpage where I downloaded the Texas county map: <http://geology.com/state-map/texas.shtml>.

The pink bollworm monitoring report due date of Dec. 31st (v. Dec. 1st) is fine.

Monsanto wished to have all Bollgard II references with the registered trademark symbol, but it looks like they missed some in their mark-up copy so you'll have to search and replace to make sure all Bollgard II references have the registered trademark symbol.

Any other tweaks Monsanto made to our proposed language are fine. I think when I sent you the draft last Thursday that I managed to remove all previous due dates that had passed and either inserted "Annually" or "beginning with Jan.31, 2008" or in the case of the natural refuge reassessment, "Jan. 31, 2012." Monsanto had no comments on any of these dates and their modifications were extremely minor.

Sharlene

Sharlene R. Matten, Ph.D.
Biologist
USEPA/OPP/BPPD (7511P)
1200 Pennsylvania Ave., NW
Washington D.C. 20460
703-605-0514
Alan Reynolds/DC/USEPA/US



Alan
Reynolds/DC/USEPA/US
05/29/2007 03:22 PM

To Mike Mendelsohn/DC/USEPA/US@EPA
cc Janet Andersen/DC/USEPA/US@EPA, Sharlene
Matten/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA
Subject Re: Fw: Final BGII terms

Mike-

Russ' updates look ok to me. It appears as though he cleaned up some of the old language (i.e. references to reports due in 2004) and more explicitly worded the restricted counties and the PBW areas.

I would defer to Sharlene for any specific comments on those PBW areas....she has a much better understanding of that region.

-Alan

Mike Mendelsohn/DC/USEPA/US



Mike
Mendelsohn/DC/USEPA/US
05/29/2007 02:41 PM

To Sharlene Matten/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA
cc Janet Andersen/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA
Subject Fw: Final BGII terms

Sharlene and Alan,

Please advise. Thanks.

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (751 tP)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
<http://www.epa.gov/pesticides/biopesticides>

----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 05/29/2007 02:39 PM -----



"SCHNEIDER, RUSSELL P
[AG/1920]"
<russell.p.schneider@mons
anto.com>
05/29/2007 01:22 PM

To Janet Andersen/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA
cc
Subject Final BGII terms

Janet/Mike/Sheryl,

Please find attached a revised draft conditions of registration for Bollgard II cotton, EPA Reg. No. 524-522 (clean copy), and a strike-out copy for your comparison. I don't think we have changed the intent of anything you proposed, but wanted to be more specific about several issues. Rather than a generic Trans Pecos region, we have stated the actual counties that are included in the pink bollworm eradication program, and since all of the eradication program does not occur in AZ and NM, we have listed the entire state to be

included in the refuge program currently in place. We have requested a delivery date on the pink bollworm information to the end of December rather than the first and other than some formatting, I think all of the language you proposed has been included.

Please let me know if you have any concerns about our response and many thanks for the quick turn-around. I think you should be able to proceed with the pre-acceptance letter.

Russ

<<Bollgard II Draft Revisions to Terms clean.doc>> <<Bollgard II Draft Revisions to Terms.doc>>

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Bollgard II Draft Revisions to Terms.doc



Mike
Mendelsohn/DC/USEPA/US
05/29/2007 02:39 PM

To: Sharlene Matten/DC/USEPA/US, Alan
Reynolds/DC/USEPA/US
cc: Janet Andersen/DC/USEPA/US, Sheryl
Reilly/DC/USEPA/US

bcc:

Subject: Fw: Final BGII terms

Sharlene and Alan,

Please advise. Thanks.

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
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(703) 308-7026 (fax)
<http://www.epa.gov/pesticides/biopesticides>
----- Forwarded by Mike Mendelsohn/DC/USEPA/US on 05/29/2007 02:39 PM -----



"SCHNEIDER, RUSSELL P
[AG/t920]"
<russell.p.schneider@monsanto.com>
05/29/2007 01:22 PM

To: Janet Andersen/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA, Mike
Mendelsohn/DC/USEPA/US@EPA
cc:

Subject: Final BGII terms

Janet/Mike/Sheryl,

Please find attached a revised draft conditions of registration for Bollgard II cotton, EPA Reg. No. 524-522 (clean copy), and a strike-out copy for your comparison. I don't think we have changed the intent of anything you proposed, but wanted to be more specific about several issues. Rather than a generic Trans Pecos region, we have stated the actual counties that are included in the pink bollworm eradication program, and since all of the eradication program does not occur in AZ and NM, we have listed the entire state to be included in the refuge program currently in place. We have requested a delivery date on the pink bollworm information to the end of December rather than the first and other than some formatting, I think all of the language you proposed has been included.

Please let me know if you have any concerns about our response and many thanks for the quick turn-around. I think you should be able to proceed with the pre-acceptance letter.

(See also e-mail)
July 5/27/07
I concur
Bollgard II with (R) Syngenta
in all places. - Same are missing
OK w/ Dec 31st date for
PBW monitoring data
OK w/ specific TX counties
- PBW res have been great

Russ

<<Bollgard II Draft Revisions to Terms clean.doc>> <<Bollgard II Draft Revisions to Terms.doc>>

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Bollgard II Draft Revisions to Terms.doc

~~5. After the registration expires, plants or plant materials that contain the plant-incorporated protectant may not be sold, or distributed.~~

The following information regarding commercial production must be included in the grower guide for Bollgard II® Cotton and is a term of this registration:

- a) No planting or sale for commercial planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) No planting or sale for commercial planting ~~Commercial culture~~ of Bollgard II cotton is permitted ~~prohibited~~ in Hawaii, Puerto Rico, and the U.S. Virgin Islands.
- c) No planting or sale for commercial planting of Bollgard II cotton is permitted ~~must not be sold for commercial planting~~ in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton intended for these purposes and is a term of this amendment:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

4.6. Insect Resistance Management Program Elements. The required IRM program for Bollgard II cotton must have the following elements:

- a. Requirements for a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II cotton ~~For Pink Bollworm Only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler; El Paso/Trans Pecos pink bollworm suppression/eradication program area of west Texas; requirements relating to creation of a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II® cotton;~~
- b. Requirements for Monsanto to prepare and require ~~Bt~~ Bollgard II cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the IRM requirements;
- c. Requirements for Monsanto to develop, implement, and report to EPA on programs to

educate growers about IRM requirements;

d. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements ~~For Pink Bollworm Only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler; El Paso/Trans Pecos pink bollworm suppression/eradication program area of west Texas: requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements;~~

e. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1Ac and Cry2Ab2 proteins in the target insects;

f. Requirements for Monsanto to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

g. Requirements for annual reports on or before January 31st each year for compliance assurance (including grower education) and sales. The tobacco budworm and cotton bollworm annual resistance monitoring reports must be submitted to EPA on or before June 30th each year and for pink bollworm, the annual resistance monitoring report must be submitted to EPA on or before December 31st each year. See Annual Reports section below.

5.7. Insect Resistance Management Requirements

a. Refuge Requirements for Pink Bollworm Resistance Management only in the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler.

All growers of Bollgard II® cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within 1/4 mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of Bollgard II® cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Btk* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* cotton refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge

~~Plant at least 5 acres of non-*Bt* cotton (refuge cotton) for every 95 acres of Bollgard II® cotton. The refuge cotton must be embedded as a contiguous block within the *Bt* cotton field, but not at one edge of the field (i.e., refuge block(s) surrounded by Bollgard II® cotton). For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the *Bt* cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*Bt* cotton may be utilized as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II® cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II® cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II® cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage-feeding caterpillars.~~

3) Embedded Refuge for Pink Bollworm Only

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard II cotton. ~~There is no field unit option.~~

- b. Natural Refuge Requirements for Tobacco Budworm and Cotton Bollworm Resistance Management only in the states of Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas (excluding the following counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler), and Virginia. ~~from the State of Texas to the East Coast (states of Texas, Oklahoma, Kansas, Arkansas, Louisiana, Missouri,~~**

~~Tennessee, Mississippi, Alabama, Georgia, Florida, South Carolina, North Carolina, Virginia)~~

- 1) Tobacco budworm sampling must be conducted for at least one year in west Texas, Alabama, and Tennessee. An appropriate gossypol analysis, statistical analysis, calculation of effective and natural refuge, and simulation modeling must be performed to determine the likelihood of tobacco budworm resistance to the Cry1Ac and Cry2Ab2 proteins expressed in Bollgard II® cotton using natural refuge. Previously, these states had only a single year of sampling data and analysis to support the natural refuge. The new data collected in 2007 and/or 2008 must be compared with previously collected data (2004 to 2006, depending on the location) to confirm ~~that~~ the effectiveness of a natural refuge. A report of these findings must be submitted to EPA on or before January 31st following the year of collection.

- 2) Monsanto must submit data to EPA by January 31st, 2012, and every five years thereafter, to support an EPA reassessment of the natural refuge and to confirm its effectiveness with tobacco budworm and cotton bollworm. The data must include: resistance monitoring data, cropping pattern analysis, and simulation modeling to reexamine levels of effective refuge in the states of **Alabama, Arkansas, Florida, Georgia, Kansas, Kentucky, Louisiana, Maryland, Missouri, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, and Virginia** ~~Texas, Oklahoma, Kansas, Arkansas, Louisiana, Missouri, Tennessee, Mississippi, Alabama, Georgia, Florida, South Carolina, North Carolina, Virginia~~. Both cropping and land use patterns can change over time, which could impact the amount of natural refuge available to tobacco budworm and cotton bollworm relative to cotton. If based on this reassessment, EPA determines that additional tobacco budworm and/or cotton bollworm sampling, gossypol analysis, statistical analysis, and simulation modeling are needed to justify continuation of the natural refuge, Monsanto must submit these ~~this~~ data within the EPA requested timeframe. If EPA's assessment concludes that the natural refuge is no longer scientifically supported, Monsanto agrees to submit an application to amend the registration to restore the structured refuge requirements ~~that were up until now~~ previously required for tobacco budworm and cotton bollworm uses. start
Cm-ty
w/o

- 3) It is recommended that Monsanto develop a more complex, spatial model of resistance for Bollgard II cotton that further considers the evolution of resistance "hotspots" (i.e. localized areas of resistance) and provide EPA with this information. Key issues like spatial structure, linkage disequilibrium, and differential movement of males and females have not yet been explored in detail for pyramided Bt proteins. Such models would be more desirable to examine the resistance evolution at the local level where natural refuge may be limited for one or more generations of tobacco budworm.

b. Grower Agreements

While Monsanto will have flexibility to design its program to fit its own business practices, the registration is specifically conditioned on meeting the following requirements.

1) Persons purchasing the Bollgard II cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must continue to implement an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use an approved grower agreement. If Monsanto wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this amendment.

5) Monsanto must continue an approved system which is reasonably likely to assure that persons purchasing the Bollgard II cotton sign grower agreement(s).

6) Monsanto shall maintain records of all Bollgard II cotton grower agreements for a period of three years from December 31st of the year in which the agreement was signed.

7) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of the Bollgard II cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior October through September. ~~Note: the first report shall contain the specified information for the time frame starting with the date of registration and ending September 30, 2004.~~

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

c. IRM Education and IRM Compliance Monitoring Programs

Monsanto must implement the following IRM education and compliance monitoring programs:

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bollgard II cotton users the importance of complying with the IRM program. The program shall include information encouraging Bollgard II cotton users to pursue optional elements of the IRM program relating to refuge configuration and

proximity to Bollgard II cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each Bollgard II® cotton grower separate from the grower agreement. Monsanto shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Annually, Monsanto shall provide a report to EPA any substantive changes to the grower education activities as a part of the overall IRM compliance assurance program report.

~~4) For Pink Bollworm only in the states of Arizona, California, and New Mexico and in the El Paso/Trans Pecos pink bollworm suppression/eradication program area of west Texas. For pink bollworm resistance management only in the states of Arizona, California, and New Mexico and in the El Paso/Trans Pecos pink bollworm suppression/eradication program area of west Texas.~~

Monsanto shall continue to implement an ongoing, approved IRM compliance assurance program in the states of Arizona, California, and New Mexico and in the following Texas Counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler. The program is designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Bollgard II® cotton product. Other required features of the program are described in paragraphs 5 - 12 below.

5) Monsanto shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bollgard II cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bollgard II cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto shall provide a written summary of the results of the prior year's survey to EPA by January 31st of each year. Monsanto shall confer with EPA on the design and content of the survey prior to its implementation.

7) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto will confer with the Agency prior to adopting any changes.

8) Monsanto must conduct an annual on-farm assessment program. Monsanto shall train its representatives who make on-farm visits with Bollgard II® cotton growers to perform assessments of compliance with IRM requirements. There is no minimum cotton acreage size for this program. Therefore, growers will be selected for this program from across all farm sizes. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

9) Monsanto shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

10) If a grower, who purchases Bollgard II cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

11) Beginning January 31, 2008 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto, the number of tips investigated, the percent of growers who were not complying with the IRM requirements, and the follow-up actions taken.

12) Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

d. Insect Resistance Monitoring.

Monsanto must conduct an annual resistance monitoring program for *Heliothis virescens* (tobacco budworm) *Helicoverpa zea* (cotton bollworm), and *Gossypiella pectinophora* (pink bollworm) for the CryI Ac and Cry2Ab2 toxins expressed in Bollgard II cotton as early as possible. Resistance monitoring programs must include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following terms and conditions:

- 1) Monsanto must submit a revised Bollgard II cotton (Cry2Ab2 and Cry1Ac toxins) resistance monitoring plan for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm) to EPA by September 1, 2007. A revised resistance monitoring plan approved by EPA must be used beginning in the 2008 growing season. The monitoring program must include increased sampling for tobacco budworm and cotton bollworm in the areas that have the greatest variability and potentially lowest levels of effective natural refuge. Sampling efforts should include all of the "worst-case" counties identified in Monsanto's 2004 to 2006 analyses of natural refuge in the states of Texas, Tennessee, Mississippi, Louisiana, Arkansas, Alabama, Georgia, and North Carolina. BPPD believes that resistance monitoring for tobacco budworm and cotton bollworm resistance to Cry1Ac and Cry2Ab2 will have added importance with adoption of a natural refuge as a resistance management strategy.
- 2) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest.
- 3) The following testing scheme for survivors of the diagnostic or discriminating concentrations (or identified survivors of any resistance detection method) must be implemented: 1) Determine if the observed effect is heritable; 2) Determine if the increased tolerance can be observed in the field (i.e., survive on Bollgard II® cotton plants); 3) Determine if the effect is due to resistance; 4) Determine the nature of resistance (dominant, recessive); 5) Determine the resistance allele frequency; 6) Determine, in subsequent years, whether the resistance allele frequency is increasing; and 7) Determine the geographic extent of the resistance allele (or alleles) distribution. Should the resistance allele frequency be increasing and spreading, a specific remedial action plan should be designed to mitigate the extent of Bt resistance. See section e. ("Remedial Action Plans") below.
- 4) Monsanto must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, cotton leafperforator and European corn borer. Monsanto will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto will investigate all damage reports. See Remedial Action Plans section below.
- 5) Monsanto must provide to EPA for review and approval any revisions to the tobacco budworm, cotton bollworm, and pink bollworm resistance monitoring plans prior to their implementation.

- 6) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.

e. Remedial Action Plans

Specific remedial action plans are required for Bollgard II® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto must implement the Arizona *Bt* Cotton Working Group's Remedial Action Plan. Monsanto must obtain approval from EPA before modifying the Arizona *Bt* Cotton Working Group's Remedial Action Strategy.

2) Remedial (Mitigation) Action Plan for Tobacco Budworm and Cotton Bollworm

If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto must implement the Remedial Action Plan approved by EPA. Monsanto must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

f. Annual Reports for Sales, Grower Education, Compliance Assurance, Grower Agreements, and Resistance Monitoring.

Annually by January 31st, Monsanto will provide EPA a report that contains the following information: number of units of the Bollgard II® cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements, results of the compliance assurance program including any substantive changes to the grower education program, and a sales report. The annual sales report should contain a summary of all Bollgard II cotton sales summarized by state (county level information available upon request) except for the ten restricted counties in Texas; in those counties, Monsanto must provide county-level sales information.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for tobacco budworm and cotton bollworm and by December 31st each year for pink bollworm for the duration of this registration.



ht



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 18, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MONSANTO COMPANY
1300 I STREET, NW, SUITE 450 EAST
WASHINGTON, DC 20005

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 16-MAY-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

May 16, 2007

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Biopesticide and Pollution Prevention Division

Subject: Supplemental information requested in support of natural refuge amendment request for Bollgard II[®] cotton submitted November 15, 2006 (EPA Reg. No. 524-522).

Dear Dr. Reilly:

On May 10, 2007, Mike Mendelsohn at EPA BPPD requested additional information to support the review of the natural refuge amendment request submitted by Monsanto Company for Bollgard II[®] cotton in November 2006. This letter constitutes the submission of that additional information. Attached are the following:

- Transmittal Document
- Application for Pesticide Amendment (EPA Form 8570-1)
- Volume 1 of 1: Report entitled: "Monsanto's Response to U.S. EPA Questions on Natural Refuge Modeling and Statistical Analysis" (three copies)

If you have any questions regarding this letter, please contact me directly at 314-694-7556 or through Dr. Russ Schneider at 202-383-2866.

Sincerely,

Melinda C. McCann
Cotton Regulatory Affairs Manager

cc: Mike Mendelsohn
Alan Reynolds
Russell Schneider

[®] Bollgard II is a registered trademark of Monsanto Technology LLC.

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

**REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS
SUBMITTED**

Supplemental information requested in support of natural refuge amendment request for
Bollgard II[®] cotton submitted November 15, 2006

EPA Reg. No. 524-522

TRANSMITTAL DATE

May 16, 2007

LIST OF SUBMITTED DOCUMENTS

Volume 1: Head, G. P. and Gustafson, D. I. 2007. Monsanto's Response to U.S. EPA
Questions on Natural Refuge Modeling and Statistical Analysis.
04-CT-133E-20. An unpublished study conducted by Monsanto Company.

MRID Number

47131201

COMPANY NAME:

Monsanto Company

COMPANY OFFICIAL:



Melinda C. McCann, Regulatory Affairs Manager

DATE:

May 16, 2007

COMPANY CONTACT:

Dr. Russell Schneider (202) 383-2866

[®] Bollgard II is a registered trademark of Monsanto Technology LLC.

Administrative

Materials



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier
Number

Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 524-522	2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Bollgard II cotton	PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section – II

<input type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input checked="" type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted November 15, 2006 (EPA Reg. No. 524-522).


Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt. No. per Container	If "Yes" Package wgt. No. per Container		<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other	(Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other	

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Dr. Russell P. Schneider		Title Regulatory Affairs Director		Telephone No. (Include Area Code) (202) 383-2866	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					Date Application Received (Stamped)
2. Signature <i>Melinda C. McCann</i>		3. Title Regulatory Affairs Manager			
4. Typed Name Melinda C. McCann Tel. (314) 694-7556		5. Date May 16, 2007			

Sharlene
Matten/DC/USEPA/US
05/17/2007 01:00 PM

To Mike Mendelsohn/DC/USEPA/US@EPA, Alan
Reynolds/DC/USEPA/US@EPA, Janet
Andersen/DC/USEPA/US@EPA, Sheryl
cc
bcc
Subject Re: Natural Refuge Progress Update and Recommendations


I recommend reading the full review (see attached, May 3 2007 review done by Alan and myself) to see all of the conclusions and recommendations before meeting with Monsanto (Pages 1-4 of the review -- 9 conclusions and recommendations). I also recommend we should perhaps sit down again to go over this information. The new submission addresses two pieces of confirmatory data/explanation regarding the statistical analysis for the gossypol data (points # 5 and #6 in our review). This is what Alan and I will be reviewing between now and Monday. Michael has indicated that we will have our finished review by Monday afternoon following my final review.

However, here are some important points to consider (#1, #3, #8, #9, in particular, from p. 1-4 of the review).

1) intensified resistance monitoring and cropping pattern analyses every five years (this is very critical.

2) additional confirmatory sampling data (and analyses) in certain areas in which there was higher uncertainty (i.e., Alabama, W. Texas, Tennessee in which had only a single year of sampling data and analyses) (we need this to reduce the overall uncertainty of our analyses in all cotton growing areas).

3) annual sales data reports by state (with county information available upon request by the Agency) with the 10 counties in TX reporting (we need to have some mechanism to see how Boligard II plantings are distributed throughout the cotton belt to determine natural refuge and also pinpoint areas in which we might need additional or more intensified sampling -- both for cropping pattern analysis and resistance monitoring).

SRM




BPPDreview50307.doc

Sharlene R. Matten, Ph.D.
Biologist
USEPA/OPP/BPPD (7511P)
1200 Pennsylvania Ave., NW
Washington D.C. 20460
703-605-0514
Mike Mendelsohn/DC/USEPA/US



Mike
Mendelsohn/DC/USEPA/US
05/17/2007 12:35 PM

To Janet Andersen/DC/USEPA/US@EPA
cc Alan Reynolds/DC/USEPA/US@EPA, Sharlene
Matten/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA
Subject Re: Natural Refuge Progress Update 

Janet,

If you see can see Alan's draft and Sharlene's final by Monday afternoon, will a Wednesday meeting work? Alan has said he should have the draft done Friday and Sharlene has said she would have the final done Monday afternoon. I will forward the original review that was finished May 3rd FYI.

Mike

Janet Andersen/DC/USEPA/US

Janet
Andersen/DC/USEPA/US
05/17/2007 12:19 PM

To: Mike Mendelsohn/DC/USEPA/US@EPA
cc: Alan Reynolds/DC/USEPA/US@EPA, Sharlene
Matten/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA
Subject: Re: Natural Refuge Progress Update

I think I will need to see Alan's review as the draft and then Sharlene's final to have enough time to be ready for a Wed meeting.

to -----Sent by EPA Wireless E-Mail Services.

Mike Mendelsohn

----- Original Message -----

From: Mike Mendelsohn
Sent: 05/17/2007 12:15 PM
To: Janet Andersen
Cc: Alan Reynolds; Sharlene Matten; Sheryl Reilly
Subject: Re: Natural Refuge Progress Update

Janet, and Sheryl,

Your schedules were free from 11-12 on Wed the 23rd. Will this work for you?

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution
Prevention Division (7511P)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax)
<http://www.epa.gov/pesticides/biopesticides>



"SCHNEIDER, RUSSELL P
[AG/1920]"
< russell.p.schneider@monsanto.com >

05/11/2007 12:21 PM

To: Mike Mendelsohn/DC/USEPA/US@EPA
cc: Janet Andersen/DC/USEPA/US@EPA, Sheryl
Reilly/DC/USEPA/US@EPA, Sharlene
Matten/DC/USEPA/US@EPA, Alan

bcc:

Subject: RE: Natural Refuge Amendment

WE plan to have the requested information to you by Wednesday, May 16.
This should not create any delays.

Russ

-----Original Message-----

From: Mendelsohn.Mike@epamail.epa.gov
[mailto:Mendelsohn.Mike@epamail.epa.gov]
Sent: Thursday, May 10, 2007 4:03 PM
To: SCHNEIDER, RUSSELL P [AG/1920]
Cc: Andersen.Janet@epamail.epa.gov; Reilly.Sheryl@epamail.epa.gov;
Matten.Sharlene@epamail.epa.gov; Reynolds.Alan@epamail.epa.gov
Subject: Natural Refuge Amendment

Russ,

Per our discussion this afternoon, BPPD management would like to know when Monsanto can respond to the questions raised below. Based on your response and on the timeframe for Monsanto submission of this information, we can determine the best time to meet and further discuss the natural refuge amendment and whether we need to discuss a renegotiation of the PRIA date.

Best Regards,

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution Prevention
Division (7511P) U.S. Environmental Protection Agency 1200 Pennsylvania
Avenue NW Washington DC 20460
(703) 308-8715
(703) 308-7026 (fax) <http://www.epa.gov/pesticides/biopesticides>

Address a potential subsampling bias in the gossypol testing. Subsets of 10 moths were tested from each trap, unless the proportion of gossypol positive moths exceeded 90%, in which case an additional set of ten moths was analyzed. The Science Advisory Panel report noted that this procedure could induce an upward bias for detecting non-cotton origin TBW. Monsanto should rerun the analysis (natural refuge calculations) excluding all of the additional subsets from traps with >90% cotton-origin TBW.


Provide additional clarification for the statistical analyses, particularly the data pooling criteria. For the first level of pooling (individual traps across multiple sampling dates within a month), BPPD observed that the level of significant variability (8.3%) exceeded the rejection threshold (5%) established by the company, although the data were still pooled. BPPD is concerned

that Monsanto's decision to pool individual trap data was predetermined, so that the 2006 data would better fit the structure of previous year's data. For the second level of pooling (all traps within a county for each sampling month), much of the description in Monsanto's report was unclear and seemingly contradictory. Also, no explanation or criteria was provided as to why the chi-square test was used (instead of the Fisher's Exact Test) for some of the traps. Given the importance of data pooling for the estimation of natural refuge, Monsanto should resubmit the discussion of the statistical analysis to address the questions raised above. This resubmission should include a clear description of the criteria used for Fisher's Exact Test (or chi-square) analysis, the rationale(s) for excluding traps from the testing, and justification for pooling when significant (>5%) variability was observed.

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Natural Refuge for Bollgard II



**Alan Reynolds, M.S. and
Sharlene R. Matten, Ph.D.**

U.S. EPA, Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
Washington, DC

United States Environmental Protection Agency ¹

Estimating Cotton Bollworm and Tobacco Budworm Natural Refuge

Sample insects (CBW or TBW) at many locations

↓
Chemical analysis i.e., stable isotope analysis or gossypol assay

↓
% derived from cotton

↓
Compensate for the impact of Bt cotton using estimates of adoption

↓
Current % of effective refuge

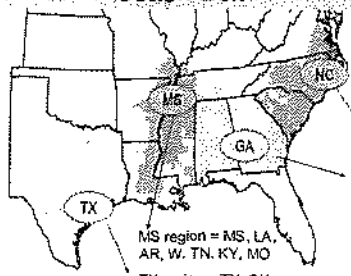
↓
Calculate non-cotton contribution assuming no non-Bt cotton exists

↓
% of natural refuge

↓
Modeling for estimating resistance

United States Environmental Protection Agency ²

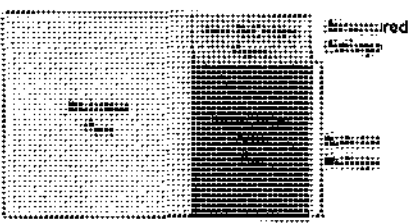
Four Sampling Regions in the Southeastern Cotton Belt



NC region = NC, SC, VA
GA region = GA, Mid-TN, FL, AL
MS region = MS, LA, AR, W. TN, KY, MO
TX region = TX, OK, W. LA, KS, W. AR

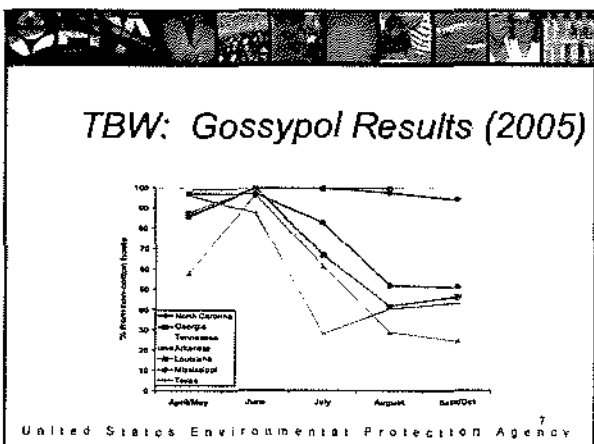
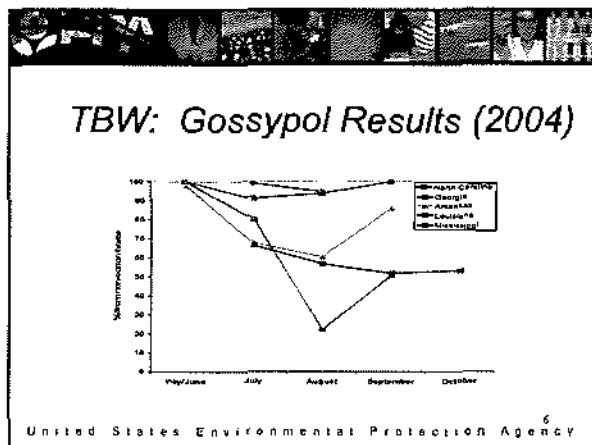
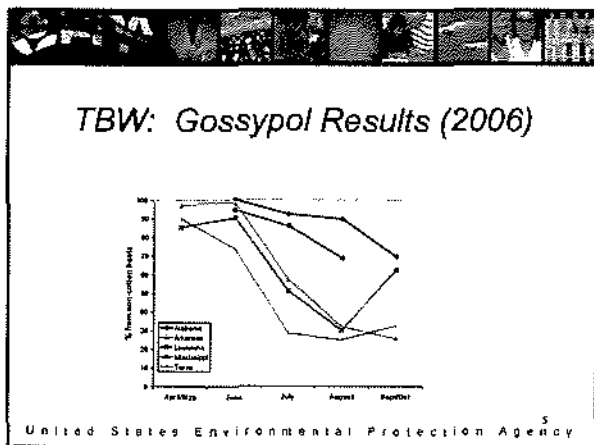
United States Environmental Protection Agency ³

Schematic of Three Sub-compartment Refuge Model for TBW




Georgia, Arkansas, Louisiana, Mississippi, North Carolina, Texas, Alabama, Tennessee

United States Environmental Protection Agency ⁴




- ### SAP Checklist
- Gossypol Method Validation
 - Peer-reviewed publication of the method and independent lab validation completed; no further data or validation are needed.
 - TBW Sampling (i.e. some areas were undersampled)
 - Additional sampling performed in 2006 for Alabama, Arkansas, Louisiana, Mississippi – similar trends as observed in 2004-5.
 - Two year sampling (2004-5) in Georgia and North Carolina is adequate.
 - Alabama, Tennessee, and west Texas have only one year of TBW sampling.
 - Potential Biases in Sampling and Gossypol Bioassays
 - Two sources of bias (non-random sampling and the discounting of traps with no captures) were adequately addressed by Monsanto.
 - Subsampling bias (i.e. extra sets of 10) was not addressed by Monsanto.
- United States Environmental Protection Agency



SAP Checklist

- 4) Statistical Analyses (i.e. more robust tests needed)
 - Monsanto utilized a generalized linear model (GLM) to analyze the gossypol data (SAP recommendation).
 - BPPD has remaining questions regarding the data pooling criteria and descriptions of the statistics in the report.
- 5) Modeling (i.e. correction and recalculations needed)
 - Models were re-run with corrections showing same or better durability as previous modeling.


United States Environmental Protection Agency ⁹



Options and Recommendations

- 1) Approve natural refuge for all of the Southeast with no conditions
- 2) Approve natural refuge for all of the Southeast with conditions (i.e. confirmatory data) (**IRM Team Preferred Option**):
 - Additional sampling in Alabama, Tennessee, and west Texas;
 - Address the potential subsampling bias;
 - Address questions regarding the statistical analyses;
 - Improved monitoring for Cry1Ac and Cry2Ab2 (Bollgard II toxins);
 - Cropping pattern analysis after 5 years (and every 5 years thereafter);
 - Reassessment of natural refuge no later than 5 years to include monitoring and cropping pattern analysis.

United States Environmental Protection Agency ¹⁰



Options and Recommendations

- 3) Approve natural refuge for states in which the greatest certainty.
 - North Carolina and Georgia (greatest certainty)
 - Arkansas, Louisiana, Mississippi (less certainty)
 - Confirmatory sampling required for remaining states (AL, TX, TN) prior to approval.
 - Other data from #2 required conditionally
- 4) Do not approve natural refuge without the additional data from #2

United States Environmental Protection Agency ¹¹



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

February 22, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MONSANTO CO
MONSANTO COMPANY
1300 I STREET, NW, SUITE 450 EAST
WASHINGTON, DC 20005

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 16-FEB-07. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



MONSANTO COMPANY
800 NORTH LINDBERGH BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

February 14, 2007

Document Processing Desk
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Branch Chief
Biopesticide and Pollution Prevention Division

Subject: Supplemental information requested in support of natural refuge amendment request for Bollgard II[®] cotton submitted November 15, 2006 (EPA Reg. No. 524-522).

Dear Dr. Reilly:

On December 7, 2006, EPA sent Monsanto Company a deficiency letter on the Bollgard II cotton (EPA Reg. No. 524-522) natural refuge amendment, which was submitted November 15, 2006 (MRID 46982001). The purpose of this letter is to address the deficiencies noted.

Point #1 in the deficiency letter requested documentation of acceptance of the gossypol analytical method manuscript by a scientific journal. In early November 2006, Monsanto submitted a manuscript describing the gossypol analytical method to the *Journal of Chemical Ecology*. On February 2, 2007, the editor of *Journal of Chemical Ecology* responded that the manuscript had been accepted for publication after minor revisions.

Point #2 in the deficiency letter requested independent laboratory validation of the gossypol analytical method. Covance Laboratories Inc. conducted a validation of the gossypol analytical method and their report is included in this submission.

Attached are the following:

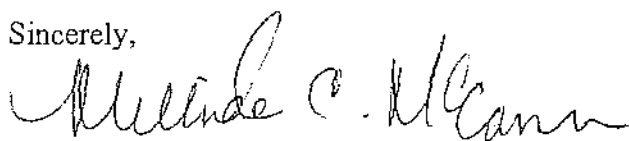
- Transmittal Document
- Application for Pesticide Amendment (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)

[®] Bollgard II is a registered trademark of Monsanto Technology LLC.

- Volume 1 of 1: Report entitled: "Independent Laboratory Validation and Publication of Gossypol Determination Method for Adult Lepidoptera" (three copies)

Should you have any questions with regard to this supplemental information please contact me at
314-694-7556 or Dr. Russell Schneider at 202-383-2866.

Sincerely,



Melinda C. McCann
Regulatory Affairs Manager, Cotton

cc: Sharlene Matten
Alan Reynolds
Russell Schneider

TRANSMITTAL DOCUMENT

SUBMITTED BY
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

**REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS
SUBMITTED**

Supplemental information requested in support of natural refuge amendment request for
Bollgard II® cotton submitted November 15, 2006

EPA Reg. No. 524-522

TRANSMITTAL DATE

February 14, 2007

LIST OF SUBMITTED DOCUMENTS

Volume 1: Head, G. P. and Orth, R. 2007. Independent Laboratory Validation and
Publication of Gossypol Determination Method for Adult Lepidoptera.
04-CT-133E-29. An unpublished study conducted by Monsanto Company.

MRID Number

47059101

COMPANY NAME:

Monsanto Company

COMPANY OFFICIAL:



Melinda C. McCann, Regulatory Affairs Manager

DATE:

February 14, 2007

COMPANY CONTACT:

Dr. Russell Schneider (202) 383-2866

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Administrative

Materials



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: February 14, 2007 EPA Reg No./File Symbol: 524-522 Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 Product: Bollgard II cotton
Ingredient *Bacillus thuringiensis* CryIAc and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G. P. and Orth, R. 2007. Independent Laboratory Validation and Publication of Gossypol Determination Method for Adult Lepidoptera. 04-CT-133E-29. An unpublished study conducted by Monsanto Company.		Monsanto Company	OWN	

Signature *Melinda C. McCann* Name and Title Melinda C. McCann Regulatory Affairs Mgr. Date February 14, 2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

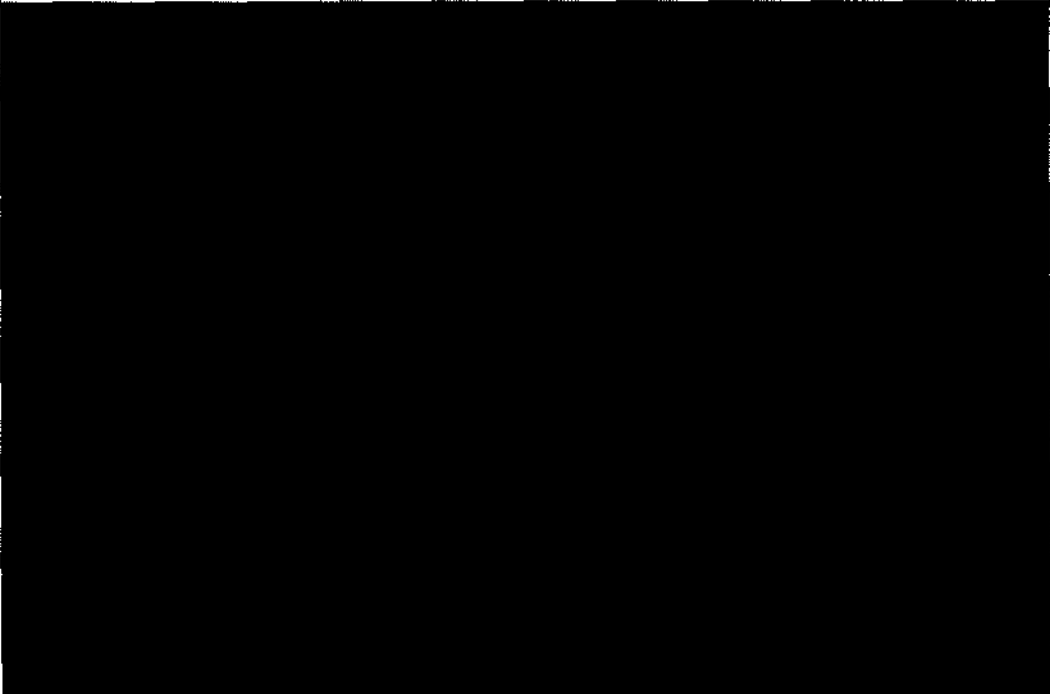
Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: February 14, 2007 EPA Reg No./File Symbol: 524-522 Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 Product: Bollgard II cotton

Ingredient *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	

Signature  Name and Title Melinda C. McCann Regulatory Affairs Mgr. Date February 14, 2007

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy



MONSANTO



MONSANTO COMPANY
1300 I (EYE) STREET, NW
SUITE 450 EAST
WASHINGTON, D.C. 20005-7211
PHONE (202) 783-2460
FAX (202) 789-1819
<http://www.monsanto.com>

December 15, 2006

U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Biopesticide and Pollution Prevention Division
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Branch Chief
Biopesticide and Pollution Prevention Division

Subject: Monsanto's Response to a Deficiency Letter from U.S. EPA, Dated 7 December 2006.

Dear Dr. Reilly:

On December 7, 2006, EPA sent Monsanto Company a deficiency letter on the Bollgard II[®] cotton (EPA Reg. No. 524-522) natural refuge amendment submitted November 15, 2006 (MRID 46982001). The deficiencies noted were:

1. Monsanto must publish the gossypol analytical method in a peer-reviewed journal.
2. Monsanto must have the gossypol analytical method validated by an independent laboratory.

On December 14, 2006, Monsanto and EPA representatives had a conference call to discuss the deficiencies noted above and Monsanto's proposed response. Participants on the call included:

EPA Participants:

Leonard Cole
Sharlene Matten
Michael McDavit
Tessa Milofsky
Sheryl Reilly
Alan Reynolds

Monsanto Participants:

Graham Head
James Jennings
Melinda McCann
Russ Schneider

As mentioned on page 10 of MRID 46982001, Monsanto submitted a manuscript describing the gossypol analytical method to the Journal of Chemical Ecology in early November 2006. Allowing the journal adequate time to review it, Monsanto estimates

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United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☒ Amendment
☐ Other

OPP Identifier
Number

Application for Pesticide – Section I

1. Company/Product Number EPA Reg. No. 524-522	2. EPA Product Manager Dr. Sheryl Reilly	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
Company/Product (Name) Bollgard II cotton	PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

Section – II

<input checked="" type="checkbox"/> Amendment – Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated
<input type="checkbox"/> Resubmission in response to Agency letter dated	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification – Explain below.	<input type="checkbox"/> Other – Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Supplemental information requested in support of natural refuge amendment request for Bollgard II cotton submitted November 15, 2006 (EPA Reg. No. 524-522).

Section – III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted	If "Yes" Unit Packaging wgt.	No. per Container	If "Yes" Package wgt.	No. per Container	<input type="checkbox"/> Plastic
					<input type="checkbox"/> Glass
					<input type="checkbox"/> Paper
					<input type="checkbox"/> Other (Specify)
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other			

Section – IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Dr. Russell P. Schneider		Title Regulatory Affairs Director		Telephone No. (Include Area Code) (202) 383-2866	
<p align="center">Certification</p> <p>I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.</p>					
2. Signature <i>Melinda C. McCann</i>		3. Title Regulatory Affairs Manager		6. Date Application Received (Stamped)	
4. Typed Name Melinda C. McCann Tel. (314) 694-7556		5. Date February 14, 2007			



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 (202) 383-2866

EPA Registration Number / File Symbol:

Reg. No. 524-522

Active Ingredient(s) and/or representative test compound(s): *Bacillus thuringiensis* Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in cotton

Date:

February 14, 2007

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158:

Terrestrial field crop

Product Name:

Bollgard II cotton

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

☒ I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature

Date

February 14, 2007

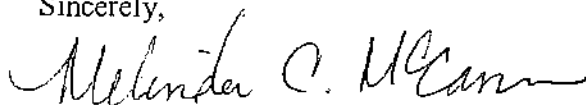
Typed or Printed Name and Title

Melinda C. McCann, Regulatory Affairs Manager

the manuscript could be accepted by the journal in February 2007. This will fulfill point # 1 in the deficiency letter. In addition, Monsanto has contacted EPA-certified analytical laboratories that may be able to conduct a validation of the gossypol analytical method. Attached to this cover letter is a proposal for validation of the gossypol analytical method by an independent party. If the EPA agrees that this proposal will address point # 2 in the deficiency letter, then Monsanto will initiate the validation study at one of the contract laboratories. The study should be completed by early February 2007.

Should you have any questions with regard to this letter please contact me at 314-694-7556 or Dr. Russell Schneider at 202-383-2866.

Sincerely,



Melinda C. McCann
Regulatory Affairs Manager, Cotton

cc: Leonard Cole
Russell Schneider

Monsanto Company Independent Laboratory Validation Proposal of Gossypol in Adult Moths

The goal of this validation study is to demonstrate the ability of the analytical method to determine if an adult moth has been raised on cotton or not raised on cotton by determining the presence of gossypol. The validation will involve three stages. The first stage is the determination of linearity and estimates of limits of detection for the instrumentation used by the laboratory. This sets the level of deuterated dianiline gossypol used as internal standard. The second stage is a training run where the contract laboratory is given a set of moths whose diet is known to contain cotton or no cotton. This stage tests the criteria for making the decision if a moth was positive (reared on cotton) or negative (not reared on cotton). The last stage is to test the accuracy and the precision of the method by carrying out a "blind" study. The contract laboratory will receive a set of coded moths that are a mixture of moths reared on cotton and moths reared on plant hosts other than cotton.

The independent validation will begin with the submission of the Standard Operating Procedure (SOP) developed by Monsanto to the contract laboratory. The contract laboratory will make the appropriate changes in the SOP to fit the instrumentation and the equipment available to them. For example, the liquid chromatography mass spectrometry/mass spectrometer (LC/MS/MS) may not be exactly the same. These changes will be incorporated into the SOP used by the laboratory.

The contract laboratory then will run the method with deuterated internal standard (deuterated aniline) to determine the amount of contribution from the small amount of non deuterated dianiline gossypol present. The laboratory will use this to adjust the level of internal standard so that this contribution is below detectable limits. Next a calibration curve using gossypol standards will be generated to show linearity and to estimate detection limits.

The contract laboratory then will be provided four moths that have been reared on cotton and four moths that have been reared on a host plant other than cotton. These will be analyzed and criteria will be developed to determine whether a moth has gossypol present or not. These criteria may differ from those developed by Monsanto because of differences in LC/MS/MS instrumentation (but this does not detract from the value of the analytical method).

A check of accuracy and precision then will be determined by submitting 12 moths that have been reared on plants other than cotton and 12 moths reared on cotton. These will be coded randomly (blind) and mixed together. The contract laboratory also will run method blanks and solvent blanks along with the experimental unknowns. The criteria set above will be used to determine the positive moths (reared on cotton) and the negative moths (reared on plants other than cotton). An accuracy of 100% will be the correct identification of the diet for each moth. Precision will be indicated by the percentage of false positives or negatives obtained; because the decision criteria are set conservatively, there should be no false negatives but there may be a low rate of false positives.

Summary Title

Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel
Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts
for Monsanto's Bollgard II Cotton

Data Requirement

Required in support of the registration amendment for Bollgard II cotton

EPA Reg. No. 524-522

Authors

Graham P. Head, Ph.D.

Registrant Submitting Date

November 10, 2006

Registrant Submitting

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Submission ID

06-RA-36-02
04-CT-133E-12

Volume 1 of 1

MONSANTO



MONSANTO COMPANY
800 NORTH LINCOLN BLVD
ST. LOUIS, MISSOURI 63167
<http://www.monsanto.com>

November 10, 2006

U.S. Environmental Protection Agency
Office of Pesticide Programs (7504P)
Biopesticide and Pollution Prevention Division
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

To: Dr. Sheryl Reilly, Branch Chief, Microbial Pesticides Branch

Subject: Application to amend the registration for Bollgard II[®] cotton, EPA Reg. No. 524-522.

Dear Dr. Reilly:

On September 27, 2006, EPA granted Monsanto Company an unconditional registration for Bollgard II cotton. In this application, Monsanto is seeking to amend that registration by seeking to remove the current refuge requirements and replace them with an unstructured or natural refuge for the U.S. Cotton Belt from Texas to the East Coast.

Monsanto previously submitted reports to the EPA on December 22, 2005, in support of a natural refuge for Bollgard II cotton. A summary of those reports follows.

1. A report for tobacco budworm (TBW; MRID 46717201) concluded significant portions of adult TBW populations in all regions of the U.S. Cotton Belt originate from alternative non-cotton hosts.
2. Taking results from the TBW report and previously generated data on alternate host use of cotton bollworm (CBW) and TBW, Monsanto used mathematical models to evaluate the potential of non-cotton alternative hosts of CBW and TBW to provide a sufficient natural refuge for Bollgard II cotton (MRID 46717202). For CBW, Bollgard II cotton retained its efficacy against CBW for more than 25 years in all of the 56 cases modeled. For TBW, Bollgard II cotton retained its efficacy for more than 30 years in all 98 cases modeled. Overall, the modeling results demonstrated that Bollgard II cotton should have more than 25 years of durability for the control of CBW and TBW in all regions (Texas to the East Coast) with natural refuge as the only source. This conclusion is valid under a wide variety of product adoption and management scenarios, even though the modeling is highly conservative in its assumptions.
3. Included was also a report on the scientific and economic justification for not requiring a structured refuge (MRID 46717203).

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On May 15, 2006, EPA issued their review of the data submitted December 22, 2005 and convened a Scientific Advisory Panel (SAP) on June 13-14, 2006. The meeting minutes from the SAP were issued on September 8, 2006; and in support of this amendment application, Monsanto is submitting a response to the SAP minutes. These additional data provided herein and the data previously submitted and reviewed, support Monsanto's application to amend the current Bollgard II cotton registration. Attached are the following:

- Transmittal Document
- Application for Pesticide Amendment (EPA Form 8570-1)
- Certification with Respect to Citation of Data (EPA Form 8570-34)
- Data Matrix (EPA Form 8570-35)
- Product Label with proposed changes (five copies)
- Volume 1 of 1: Report entitled: "Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts for Monsanto's Bollgard II Cotton" (three copies)

In the attached report, Monsanto addresses all of the questions and recommendations identified by the SAP with new data and important clarifications of specific elements from the original submission of December 22, 2005. Published and new data on the nature of gossypol in plants and insects confirm that the gossypol present in adult moths is in a highly stable form and does not significantly decrease as moths age for up to 11 days and/or if moths are left dead in a trap for up to a week. The risk-based sampling approach used by Monsanto is the preferred approach for assessing risk where frequencies of occurrence of TBW, or the levels of non-cotton host contribution to TBW populations, may be very low. Sampling sites were selected based on objective criteria that focused on higher risk areas. The additional year of results are very consistent with the data and conclusions from 2004 and 2005, and confirms the relatively high non-cotton contribution to TBW populations throughout the cotton growing regions from Texas to the East Coast.

Reanalysis of the data from the 2004 and 2005 field seasons confirmed the original conclusions and produced estimates of non-cotton host contribution that were not significantly different from those used for the original resistance modeling. Analyses of the 2006 data also support the analyses and conclusions in the original submission. New statistical analyses of the 2004, 2005, and 2006 data were used to generate even more conservative model inputs and the model output was enhanced to provide greater sensitivity, but the conclusions of the models were not affected. The revised modeling produces conclusions that are supported by independent modeling efforts from three different sources using very different models. The results from all of these models and

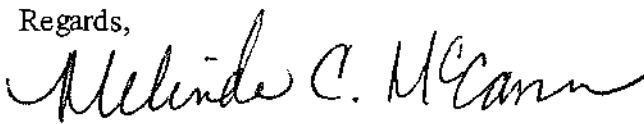
analyses consistently support the conclusion that the natural refuge for TBW from Texas to the East Coast will ensure greater than 30 years of durability for Bollgard II cotton.

Data available in the literature, provided in the original submission, and in this submission conclusively detail the support for a natural refuge for Bollgard II cotton as a viable refuge option to maintain a sustainable delay in CBW and TBW resistance development. In addition, allowing for a natural refuge option for Bollgard II cotton will have three significant benefits: (1) reduced insecticide use with favorable associated environmental effects, (2) a reduced risk of the development of insect resistance to conventional insecticides (particularly pyrethroids), and (3) improved profitability for the grower. These benefits and a natural refuge provide a strong incentive for growers to transition to Bollgard II cotton, further minimizing the risk of insect resistance in the field.

On June 2, 2005, the Federal Register published a notice from the EPA regarding fees and decision times for plant-incorporated protectant registrations [FR 70(105): 32334-32335]. All the necessary data for the active ingredient have been reviewed and approved under the existing Bollgard II cotton end-use product registration, and we are requesting only an amendment to the current registration. Therefore, the proposed amendment to the registration of Bollgard II cotton requested in this application would be most closely described by category B90 (amendment, non-fast-track).

Should you have any questions with regard to this application please contact me at 314-694-7556 or Dr. Russell Schneider at 202-383-2866.

Regards,



Melinda C. McCann
Regulatory Affairs Manager, Cotton

cc: Leonard Cole
Russell Schneider

TRANSMITTAL DOCUMENT

SUBMITTED BY

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

**REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS
SUBMITTED**

Application to amend the registration for Bollgard II[®] cotton

EPA Reg. No. 524-522

TRANSMITTAL DATE

November 10, 2006

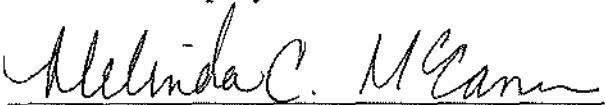
LIST OF SUBMITTED DOCUMENTS

Volume I: Head, G. P. 2006. Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts for Monsanto's Bollgard II Cotton
An unpublished study conducted by Monsanto Company.

MRID Number _____

COMPANY NAME: Monsanto Company

COMPANY OFFICIAL:


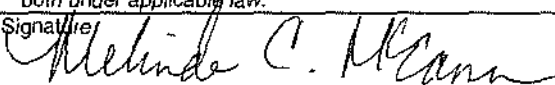


Melinda C. McCann, Regulatory Affairs Manager

DATE: November 10, 2006

COMPANY CONTACT: Dr. Russell Schneider (202) 383-2866

[®] Bollgard II is a registered trademark of Monsanto Technology LLC.

 <div style="display: inline-block; vertical-align: middle; text-align: center;"> United States Environmental Protection Agency Washington, DC 20460 </div>		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other	OPP Identifier Number
Application for Pesticide – Section I			
1. Company/Product Number EPA Reg. No. 524-522		2. EPA Product Manager Sheryl Reilly	
Company/Product (Name) Bollgard II cotton		PM # 90	
5. Name and Address of Applicant (Include ZIP Code) Monsanto Company 800 North Lindbergh Blvd. St. Louis, MO 63167 <input type="checkbox"/> Check if this is a new address		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____			
Section – II			
<div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> Amendment – Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification – Explain below. </div> <div> <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other – Explain below. </div> </div>			
Explanation: Use additional page(s) if necessary. (For section I and Section II.) Application to amend the registration of the plant-incorporated protect Bollgard II cotton to change the refuge requirements.			
Section – III			
1. Material This Product Will Be Packaged In:			
Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per Container	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No If "Yes" Package wgt. No. per Container	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____
* Certification must be submitted			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container	
5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product		6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section – IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Russell P. Schneider		Title Regulatory Affairs Director	
Telephone No. (Include Area Code) (202) 383-2866		6. Date Application Received (Stamped)	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 		3. Title Regulatory Affairs Manager	
Typed Name Melinda C. McCann Tel. (314) 694-7556		5. Date November 10, 2006	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S. W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC, 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167 (314) 694-1000	EPA Registration Number / File Symbol: Reg. No. 524-522
Active Ingredient(s) and/or representative test compound(s): <i>A Bacillus thuringiensis CryI Ac</i> and <i>Cry2Ab2</i> proteins and the genetic material necessary for their production in cotton	Date: November 10, 2006
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158: Terrestrial field crop	Product Name: Bollgard II cotton

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

Section I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix Form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

Section II: GENERAL OFFER TO PAY

☐ **Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements**
I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

Section III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for registration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

☒ I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under the applicable law.

Signature <i>Melinda C. McCann</i>	Date November 10, 2006	Typed or Printed Name and Title Melinda C. McCann, Regulatory Affairs Manager
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Form Approved OMB No. 2070-0060

401 M Street, S.W.
Washington, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 10, 2006

EPA Reg No./File Symbol: 524-522

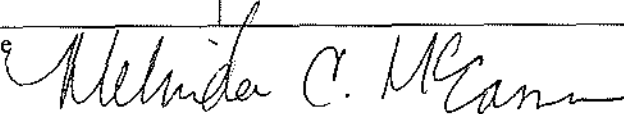
Page 1 of 1

Applicant's/Registrant's Name & Address:

Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167

Product: Bollgard II cotton

Ingredient *A Bacillus thuringiensis* CryI Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	Head, G. and Gustafson, D. 2005. Production of <i>Heliothis virescens</i> from alternative host plants and the role of these host plants as a natural refuge for Bollgard II [®] cotton. MSL-20123. An unpublished study conducted by Monsanto Company.	46717201	Monsanto Company	OWN	
	Gustafson, D. I. And Head, G. P. 2005. Modeling the impact of natural refuge on the evolution of tobacco budworm and cotton bollworm resistance to Bollgard II [®] cotton. MSL-19689. An unpublished study conducted by Monsanto Company.	46717202	Monsanto Company	OWN	
	Head, G., McCann, M. C., and Mullins, J. W. 2005. Scientific and Economic Justification for Not Requiring Structured Cotton Refuges for Bollgard II [®] Cotton in the U.S. Cotton Belt from Texas to the East Coast. MSL-20091. An unpublished study conducted by Monsanto Company.	46717203	Monsanto Company	OWN	
	Head, G. P. 2006. Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts for Monsanto's Bollgard II Cotton. An unpublished study conducted by Monsanto Company.		Monsanto Company	OWN	
Signature			Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date November 10, 2006	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
Washington, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date: November 10, 2006	EPA Reg No./File Symbol: 524-522	Page 1 of 1
Applicant's/Registrant's Name & Address: Monsanto Company, 800 North Lindbergh Blvd., St. Louis, MO 63167		Product: Bollgard II cotton

Ingredient *A Bacillus thuringiensis Cry1Ac and Cry2Ab2 proteins and the genetic material necessary for their production in Bollgard II cotton*

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	
			Monsanto Company	OWN	

Signature <i>Melinda C. McCann</i>	Name and Title Melinda C. McCann Regulatory Affairs Mgr.	Date November 10, 2006
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PRODUCT LABEL

The subject of this submission is a request to amend the registration of Bollgard II[®] cotton to change the refuge requirements to an unstructured or natural refuge for the U.S. Cotton Belt from Texas to the East Coast. Following are five copies of the Bollgard II cotton label with the proposed changes highlighted in yellow.

[®] Bollgard II is a registered trademark of Monsanto Technology LLC.

Bollgard II[®] Cotton

Plant-Incorporated Protectant Active Ingredient

Bacillus thuringiensis subsp. *kurstaki*

Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production [PV-GHBK11] in event MON 15985 cotton.....0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 15985 cotton.....0.00004-0.00052%*

Other Ingredients:

Substance produced by marker genes and the genetic material necessary for their production [PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton.0.0022-0.0304%*

* Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

[®] Bollgard II cotton is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide, which contains the following:

1. The *B.t.k.* delta endotoxin proteins expressed in this cotton control the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k.* delta endotoxin proteins are planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding commercial production must be included in the Grower Guide:

- a) No planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II cotton is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

All Bollgard II cotton growers in the states of Arizona, California, and New Mexico must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be

treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant at least 5 acres of non-*B.t.k.* cotton (refuge cotton) for every 95 acres of Bollgard II cotton. The refuge cotton must be embedded as a contiguous block within the Bollgard II cotton field. For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the Bollgard II cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*B.t.k.* cotton may be used as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit). The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton. There is no field unit option.

Bollgard II[®] Cotton

Plant-Incorporated Protectant Active Ingredient

Bacillus thuringiensis subsp. *kurstaki*

Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production [PV-GHBK11] in event MON 15985 cotton.....0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 15985 cotton.....0.00004-0.00052%*

Other Ingredients:

Substance produced by marker genes and the genetic material necessary for their production [PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton.0.0022-0.0304%*

* Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

[®] Bollgard II cotton is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide, which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins are planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding commercial production must be included in the Grower Guide:

- a) No planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II cotton is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

All Bollgard II cotton growers in the states of Arizona, California, and New Mexico must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be

treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant at least 5 acres of non-*B.t.k.* cotton (refuge cotton) for every 95 acres of Bollgard II cotton. The refuge cotton must be embedded as a contiguous block within the Bollgard II cotton field. For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the Bollgard II cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*B.t.k.* cotton may be used as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit). The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton. There is no field unit option.

Bollgard II[®] Cotton

Plant-Incorporated Protectant Active Ingredient

Bacillus thuringiensis subsp. *kurstaki*

Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production [PV-GHBK11] in event MON 15985 cotton.....0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 15985 cotton.....0.00004-0.00052%*

Other Ingredients:

Substance produced by marker genes and the genetic material necessary for their production [PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton.0.0022-0.0304%*

* Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

[®] Bollgard II cotton is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide, which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins are planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding commercial production must be included in the Grower Guide:

- a) No planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II cotton is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

All Bollgard II cotton growers in the states of Arizona, California, and New Mexico must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be

treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant at least 5 acres of non-*B.t.k.* cotton (refuge cotton) for every 95 acres of Bollgard II cotton. The refuge cotton must be embedded as a contiguous block within the Bollgard II cotton field. For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the Bollgard II cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*B.t.k.* cotton may be used as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit). The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton. There is no field unit option.

Bollgard II[®] Cotton

Plant-Incorporated Protectant Active Ingredient *Bacillus thuringiensis* subsp. *kurstaki* Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production [PV-GHBK11] in event MON 15985 cotton.....0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 15985 cotton.....0.00004-0.00052%*

Other Ingredients:

Substance produced by marker genes and the genetic material necessary for their production [PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton.0.0022-0.0304%*

* Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

[®] Bollgard II cotton is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide, which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins are planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding commercial production must be included in the Grower Guide:

- a) No planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II cotton is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

All Bollgard II cotton growers in the states of Arizona, California, and New Mexico must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be

treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant at least 5 acres of non-*B.t.k.* cotton (refuge cotton) for every 95 acres of Bollgard II cotton. The refuge cotton must be embedded as a contiguous block within the Bollgard II cotton field. For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the Bollgard II cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*B.t.k.* cotton may be used as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit). The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton. There is no field unit option.

Bollgard II[®] Cotton

Plant-Incorporated Protectant Active Ingredient

Bacillus thuringiensis subsp. *kurstaki*

Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production [PV-GHBK11] in event MON 15985 cotton.....0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 15985 cotton.....0.00004-0.00052%*

Other Ingredients:

Substance produced by marker genes and the genetic material necessary for their production [PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton.0.0022-0.0304%*

* Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

Net (Contents) _____

[®] Bollgard II cotton is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide, which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins are planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding commercial production must be included in the Grower Guide:

- a) No planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II cotton is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

All Bollgard II cotton growers in the states of Arizona, California, and New Mexico must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be

treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant at least 5 acres of non-*B.t.k.* cotton (refuge cotton) for every 95 acres of Bollgard II cotton. The refuge cotton must be embedded as a contiguous block within the Bollgard II cotton field. For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the Bollgard II cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*B.t.k.* cotton may be used as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit). The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton. There is no field unit option.

Summary Title

Monsanto's Response to Meeting Minutes of the FIFRA Scientific Advisory Panel
Meeting Held June 13-15, 2006 on the Analysis of a Natural Refuge of Non-Cotton Hosts
for Monsanto's Bollgard II Cotton

Data Requirement

Required in support of the registration amendment for Bollgard II cotton

EPA Reg. No. 524-522

Authors

Graham P. Head, Ph.D.

Registrant Submitting Date

November 10, 2006

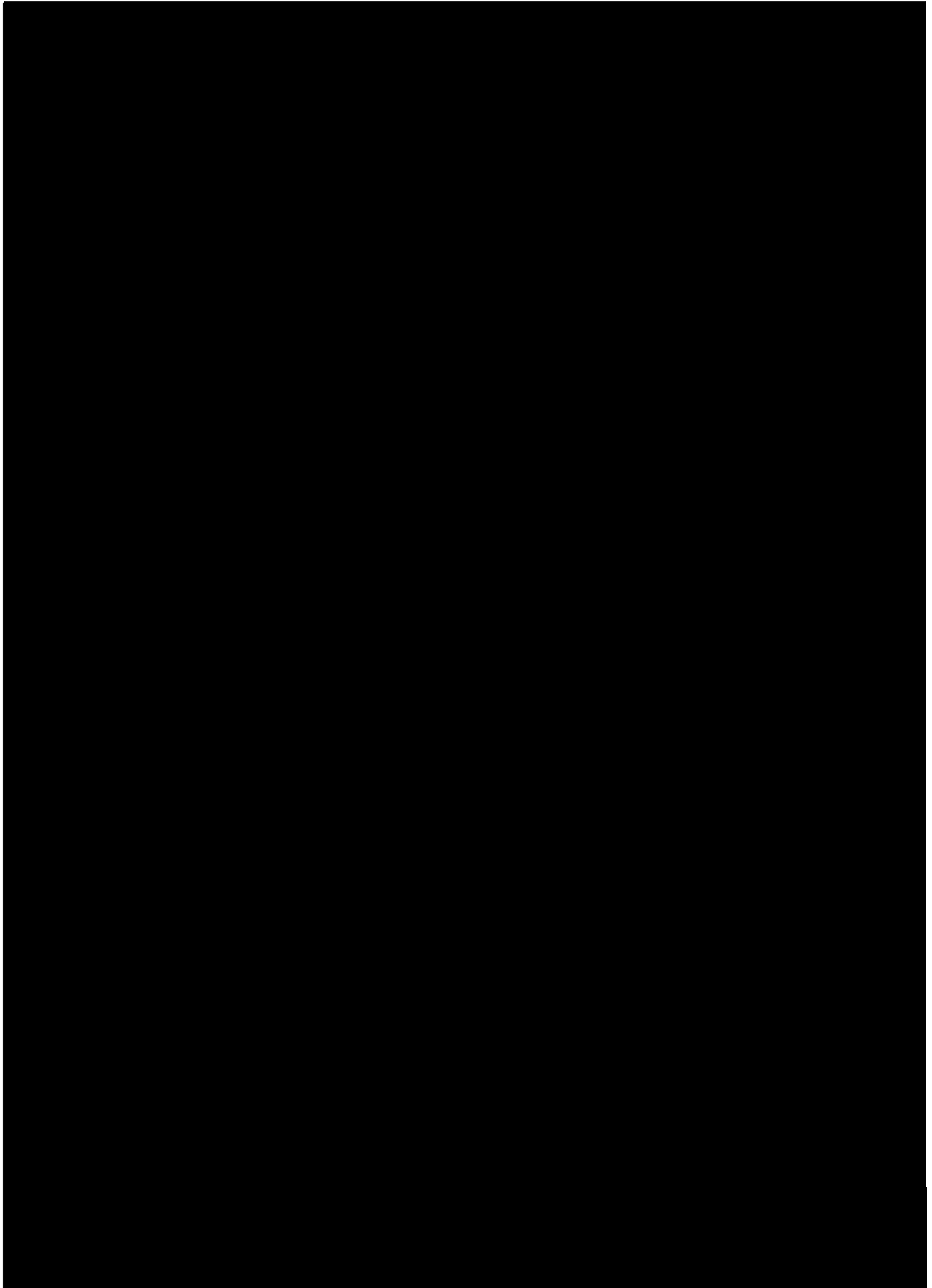
Registrant Submitting

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Submission ID

06-RA-36-02
04-CT-133E-12

Volume 1 of 1





U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

EPA
Reg.
Number:
524-522

Date of
Issuance:
9/27/06

Term of
Issuance: Unconditional

Name of Pesticide Product:
Bollgard II Cotton

Name and Address of Registrant (include ZIP Code):

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit production information for this product to Mr. Owen Beeder of Registration Division (7505P) for the fiscal year in which this product is unconditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.
3. This is an amended registration pursuant to FIFRA § 3(c)(5) and is unconditional.

Signature of Approving Official:

(See ^{last} second page for signature)

Date:

9/27/06

The following information regarding commercial production must be included in the grower guide for Bollgard II® Cotton and is a term of this amendment:

- a) No planting of Bollgard II® cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II® cotton is prohibited in Hawaii, Puerto Rico, and the US Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II® cotton intended for these purposes and is a term of this amendment:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II® cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established, test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

4. Insect Resistance Management Program Elements. The required IRM program for Bollgard II® cotton must have the following elements:

- a. Requirements relating to creation of a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II® cotton;
- b. Requirements for Monsanto to prepare and require *Bt* cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- c. Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- d. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate and promote growers' compliance with IRM requirements;

- e. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to CryI Ac and Cry2Ab2 proteins in the target insects;
- f. Requirements for Monsanto to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;
- g. Annual reports on or before January 31st each year. See Annual Reports section below.

5. Insect Resistance Management Requirements

- a. Refuge Requirements: All growers of Bollgard II® cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of Bollgard II® cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton hollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II® cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II® cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II® cotton fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of Bollgard II® cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II® cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II® cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Btk* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* cotton refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II® cotton fields.

3) Embedded Refuge

Plant at least 5 acres of non-*Bt* cotton (refuge cotton) for every 95 acres of Bollgard II® cotton. The refuge cotton must be embedded as a contiguous block within the *Bt* cotton field, but not at one edge of the field (i.e., refuge block(s) surrounded by Bollgard II® cotton). For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped

into blocks to represent a larger field unit, provided the block exists within one mile squared of the *Bt* cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*Bt* cotton may be utilized as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II® cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II® cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II® cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard II® cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II® cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard II® cotton. There is no field unit option.

b. Grower Agreements

While Monsanto will have flexibility to design its program to fit its own business practices, the registration is specifically conditioned on meeting the following requirements.

1) Persons purchasing the Bollgard II® cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must continue to implement an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use an approved grower agreement. If Monsanto wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this amendment.

5) Monsanto must continue an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton sign grower agreement(s).

6) Monsanto shall maintain records of all Bollgard II® cotton grower agreements for a period of three years from December 31 of the year in which the agreement was signed.

7) Annually, Monsanto shall provide EPA with a report on the number of units of the Bollgard II® cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior October through September.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

c. IRM Education and IRM Compliance Monitoring Programs

Monsanto must implement the following IRM education and compliance monitoring programs:

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bollgard II® cotton users the importance of complying with the IRM program. The program shall include information encouraging Bollgard II® cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bollgard II® cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each Bollgard II® cotton grower separate from the grower agreement. Monsanto shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Annually, Monsanto shall provide a report to EPA any substantive changes to the grower education activities as a part of the overall IRM compliance assurance program report

4) Monsanto shall continue to implement an ongoing, approved IRM compliance assurance program designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Bollgard II® cotton product. Other required features of the program are

described in paragraphs 5 - 12 below.

5) Monsanto shall establish and publicize a "phased compliance approach," i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bollgard cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bollgard II® cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto shall provide a written summary of the results of the prior year's survey to EPA by January 31 of each year. Monsanto shall confer with EPA on the design and content of the survey prior to its implementation.

7) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto will confer with the Agency prior to adopting any changes.

8) Monsanto shall train its representatives who make on-farm visits with Bollgard II® cotton growers to perform assessments of compliance with IRM requirements. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach," to promote compliance.

9) Monsanto shall carry out a program for investigating "tips and complaints" that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its "phased compliance approach."

10) If a grower, who purchases Bollgard II® cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

11) Annually, Monsanto shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto, the number of tips investigated, the percent of growers who were not complying with the IRM requirements, and the follow-up actions taken.

12) Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

d. Insect Resistance Monitoring.

The registration of Cry1Ac and Cry2Ab2 PIPs expressed in cotton is conditioned on Monsanto carrying out appropriate programs to detect the emergence of insect resistance as early as possible. Resistance monitoring programs include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following conditions:

1) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of tobacco budworm and cotton bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. At least 20 specific collection sites must be established in time for the 2005 growing season. Sites must be focused in areas with high risk of resistance (e.g. where adoption is at least 75% of the cotton planted in that county or parish) while overall being distributed throughout the areas where tobacco budworm and cotton bollworm are important pests. The sampling program should be segregated into different sampling regions rather than sampling within each state in which these insects are economic pests.

2) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest. Annually, Monsanto shall provide to EPA for review and approval any revisions to its resistance monitoring plan.

3) Monsanto must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, cotton leafperforator and European corn borer. Monsanto will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto will investigate all damage reports. See Remedial Action Plans section below.

4) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for the duration of the

conditional registration.

e. Remedial Action Plans

Specific remedial action plans are required for Bollgard II® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto must implement the Arizona *Bt* Cotton Working Group's Remedial Action Plan. Monsanto must obtain approval from EPA before modifying the Arizona *Bt* Cotton Working Group's Remedial Action Strategy.

2) Remedial (Mitigation) Action Plan for Tobacco Budworm and Cotton Bollworm


If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto must implement the Remedial Action Plan approved by EPA. Monsanto must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

f. Annual Reports.

Annually, Monsanto will provide an annual report to EPA on its Cry1Ac and Cry2Ab2 PIPs expressed in cotton. This report must include, but is not limited to, annual sales (both units sold and estimated acres planted) by state (units sold by county will be made available to the Agency upon request, changes in grower education, the description of grower agreements in place, grower compliance with IRM requirements, and insect resistance monitoring results).

This section 3 registration is subject to cancellation under section 6(e) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, if the terms and conditions of this registration are violated, and the company (Monsanto Company) does not comply with the terms and conditions of the registration

Sincerely,



Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division (7511P)

Bollgard II® Cotton

Bacillus thuringiensis subsp. *kurstaki* Insect Control Protein

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production
[PV-GHBK11] in event MON 15985 cotton 0.003-0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production
[PV-GHBK04] in event MON 15985 cotton 0.00004 - 0.00052%*

Other Ingredients:

Substance produced by the marker genes and the genetic material necessary for their production
[PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton..... 0.0022-0.0304%*

*Percentage (wt/wt) on a dry weight basis.

PRECAUTIONARY STATEMENT

CAUTION

KEEP OUT OF REACH OF CHILDREN

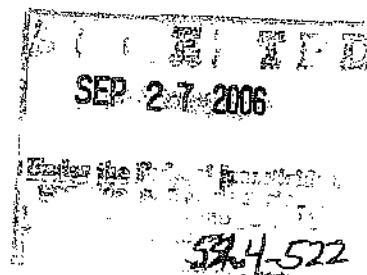
Net (Contents) _____

® Bollgard II is a registered trademark of Monsanto Technology LLC.

EPA Registration Number 524-522

EPA Establishment Number 524-MO-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167



DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin Cry1Ac and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

Bollgard II cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudophusia includens</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide which contains the following:

1. The *B.t.k.* delta endotoxin proteins expressed in this cotton control the listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k.* delta endotoxin proteins are planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. Not for commercial planting in the following counties in the Texas panhandle, which historically are not cotton-producing counties: Dallam, Sherman, Hansford, Ochiltree, Lipscomb, Hartley, Moore, Hutchinson, Roberts, and Carson.

The following information regarding commercial production must be included in the Grower Guide:

- a) No planting of Bollgard II cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II cotton is prohibited in Hawaii, Puerto Rico, and the U.S. Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

All growers of Bollgard II cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least 5 acres of non-*B.t.k.* cotton (refuge cotton) is planted for every 95 acres of Bollgard II cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. Ensure that a non-*B.t.k.* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-*B.t.k.* cotton are planted as a refuge for every 80 acres of Bollgard II cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II cotton. The non-*B.t.k.* cotton may be treated with sterile insects, insecticides (excluding foliar *B.t.k.* products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*B.t.k.* refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II cotton fields.

3) Embedded Refuge:

Plant at least 5 acres of non-*B.t.k.* cotton (refuge cotton) for every 95 acres of Bollgard II cotton. The refuge cotton must be embedded as a contiguous block within the Bollgard II cotton field. For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the Bollgard II cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*B.t.k.* cotton may be used as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit). The refuge may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every 6 to 10 rows of Bollgard II cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically at the Bollgard II cotton. There is no field unit option.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

EPA
Reg.
Number:
524-522

Date of
Issuance:

Term of
Issuance: Unconditional

Name of Pesticide Product:
Bollgard II Cotton

Name and Address of Registrant (include ZIP Code):

Monsanto Company
700 Chesterfield Parkway North
St. Louis, MO 63198

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

The registration application referred to above, submitted in connection with registration under § 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you do the following terms and conditions.

1. Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit production information for this product to Mr. Owen Beeder of Registration Division (7505C) for the fiscal year in which this product is conditionally registered, in accordance with FIFRA § 29. The fiscal year begins October 1 and ends September 30. Production information will be submitted to the Agency no later than November 15, following the end of the preceding fiscal year.
3. This is an amended registration pursuant to FIFRA § 3(c)(7)(A) and is conditional because of the outstanding Insect Resistance Management data.

CONCURRENCES

SYMBOL	7511C	Signature of Approving Official:		Date:	
SURNAME	OLE	(See second page for signature)			
DATE	9/25/05				

4. After the registration expires, plants or plant materials that contain the plant-incorporated protectant may not be sold, or distributed.

The following information regarding commercial production must be included in the grower guide for Bollgard II® Cotton and is a term of this amendment:

- a) No planting of Bollgard II® cotton is permitted south of Route 60 (near Tampa) in Florida.
- b) Commercial culture of Bollgard II® cotton is prohibited in Hawaii, Puerto Rico, and the US Virgin Islands.

The following information regarding test plots and seed production must occur on bags of Bollgard II® cotton intended for these purposes and is a term of this amendment:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within 3 miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.
- b) Experimental plots and breeding nurseries of Bollgard II® cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established, test plots or breeding nurseries, regardless of the plot size, established on the island of Puerto Rico must not be planted within 3 miles of feral cotton plants and must be surrounded by 24 border rows of a suitable pollinator trap crop.

Upon approval by EPA, test plots and/or breeding nurseries in Hawaii, the U.S. Virgin Islands, and Puerto Rico may be established without restrictions if alternative measures, such as insecticide applications, are shown to effectively mitigate gene flow.

5. Insect Resistance Management Program Elements. The required IRM program for Bollgard II® cotton must have the following elements:

- a. Requirements relating to creation of a non-*Bt* cotton refuge in conjunction with the planting of any acreage of Bollgard II® cotton;
- b. Requirements for Monsanto to prepare and require *Bt* cotton users to sign "grower agreements" which impose binding contractual obligations on the grower to comply with the refuge requirements;
- c. Requirements for Monsanto to develop, implement, and report to EPA on programs to educate growers about IRM requirements;
- d. Requirements for Monsanto to develop, implement, and report to EPA on programs to

evaluate and promote growers' compliance with IRM requirements;

e. Requirements for Monsanto to develop, implement, and report to EPA on programs to evaluate whether there are statistically significant and biologically relevant changes in susceptibility to Cry1Ac and Cry2Ab2 proteins in the target insects;

f. Requirements for Monsanto to develop, and if triggered, to implement a "remedial action plan" which would contain measures Monsanto would take in the event that any insect resistance was detected as well as to report on activity under the plan to EPA;

g. Annual reports on or before January 31st each year. See Annual Reports section below.

6. Insect Resistance Management Requirements

a. Refuge Requirements: All growers of Bollgard II® cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge

Ensure that at least 5 acres of non-*Bt* cotton (refuge cotton) is planted for every 95 acres of Bollgard II® cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs active ingredient per acre). The variety of cotton planted in the refuge must be comparable to Bollgard II® cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II® cotton. Ensure that a non-*Bt* cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the Bollgard II® cotton fields.

2) External Sprayed Refuge

Ensure that at least 20 acres of non-*Bt* cotton are planted as a refuge for every 80 acres of Bollgard II® cotton (total of 100A). The variety of cotton planted in the refuge must be comparable to Bollgard II® cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to Bollgard II® cotton. The non-*Bt* cotton may be treated with sterile insects, insecticides (excluding foliar *Btk* products), or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-*Bt* cotton refuge is maintained within at least 1 linear mile (preferably within ½ mile or closer) from the Bollgard II® cotton fields.

3) Embedded Refuge

Plant at least 5 acres of non-*Bt* cotton (refuge cotton) for every 95 acres of Bollgard II® cotton. The refuge cotton must be embedded as a contiguous block within the *Bt* cotton field, but not at one edge of the field (i.e., refuge block(s) surrounded by Bollgard II®

cotton). For very large fields, multiple blocks across the field may be used. For small or irregularly shaped fields, neighboring fields farmed by the same grower can be grouped into blocks to represent a larger field unit, provided the block exists within one mile squared of the *Bt* cotton and the block is at least 150 feet wide, but preferably 300 feet wide. Within the larger field unit, one of the smaller fields planted to non-*Bt* cotton may be utilized as the embedded refuge. The variety of cotton planted in the refuge must be comparable to Bollgard II® cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, and management of other pests) similarly to Bollgard II® cotton. This refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm whenever the entire field is treated. The refuge may not be treated independently of the surrounding Bollgard II® cotton field in which it is embedded (or fields within a field unit), except only at the pre-squaring cotton stage, when the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars.

4) Embedded Refuge for Pink Bollworm Only

Plant the refuge cotton as at least one single non-*Bt* cotton row for every six to ten rows of Bollgard II® cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *Btk* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding Bollgard II® cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the Bollgard II® cotton. There is no field unit option.

b. Grower Agreements

While Monsanto will have flexibility to design its program to fit its own business practices, the registration is specifically conditioned on meeting the following requirements.

1) Persons purchasing the Bollgard II® cotton product must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.

2) The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.

3) Monsanto must continue to implement an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton product will affirm annually that they are contractually bound to comply with the requirements of the IRM program.

4) Monsanto must continue to use an approved grower agreement. If Monsanto wishes to change any part of the grower agreement that would affect either the content of the IRM program or the legal enforceability of the provisions of the agreement relating to the IRM program, thirty days prior to implementing a proposed change, Monsanto must submit to **346**

EPA the text of such changes to ensure the agreement is consistent with the terms and conditions of this amendment.

5) Monsanto must continue an approved system which is reasonably likely to assure that persons purchasing the Bollgard II® cotton sign grower agreement(s).

6) Monsanto shall maintain records of all Bollgard II® cotton grower agreements for a period of three years from December 31 of the year in which the agreement was signed.

7) Beginning on January 31, 2005 and annually thereafter, Monsanto shall provide EPA with a report on the number of units of the Bollgard II® cotton seed shipped and not returned and the number of such units that were sold to persons who have signed grower agreements. The report shall cover the time frame of the twelve-month period covering the prior October through September. Note: the first report shall contain the specified information for the time frame starting with the date of registration and ending September 30, 2004.

8) Monsanto must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number will be kept as confidential business information.

c. IRM Education and IRM Compliance Monitoring Programs

Monsanto must implement the following IRM education and compliance monitoring programs:

1) Monsanto must design and implement a comprehensive, ongoing IRM education program designed to convey to Bollgard II® cotton users the importance of complying with the IRM program. The program shall include information encouraging Bollgard II® cotton users to pursue optional elements of the IRM program relating to refuge configuration and proximity to Bollgard II® cotton fields. The education program shall involve the use of multiple media, e.g. face-to-face meetings, mailing written materials, and electronic communications such as by internet or television commercials. The program shall involve at least one written communication annually to each Bollgard II® cotton grower separate from the grower agreement. Monsanto shall coordinate its education program with educational efforts of other organizations, such as the National Cotton Council and state extension programs.

2) Annually, Monsanto shall revise, and expand as necessary, its education program to take into account the information collected through the compliance survey required under paragraph 6 and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.

3) Beginning January 31, 2005 and annually thereafter, Monsanto shall provide a report to EPA any substantive changes to the grower education activities as a part of the overall IRM compliance assurance program report

4) Monsanto shall continue to implement an ongoing, approved IRM compliance assurance program designed to evaluate the extent to which growers are complying with the IRM program and that takes such actions as are reasonably needed to assure that growers who have not complied with the program either do so in the future or lose their access to the Bollgard II® cotton product. Other required features of the program are described in paragraphs 5 - 12 below.

5) Monsanto shall establish and publicize a “phased compliance approach,” i.e., a guidance document that indicates how Monsanto will address instances of non-compliance with the terms of the IRM program and general criteria for choosing among options for responding to any non-compliant growers. The options shall include withdrawal of the right to purchase Bollgard cotton for an individual grower or for all growers in a specific region. An individual grower found to be significantly out of compliance two years in a row would be denied sales of the product the next year.

6) The IRM compliance assurance program shall include an annual survey of a statistically representative sample of Bollgard II® cotton growers conducted by an independent third party. The survey shall measure the degree of compliance with the IRM program by growers in different regions of the country and consider the potential impact of non-response. Monsanto shall provide a written summary of the results of the prior year’s survey to EPA by January 31 of each year. Monsanto shall confer with EPA on the design and content of the survey prior to its implementation.

7) Annually, Monsanto shall revise, and expand as necessary, its compliance assurance program to take into account the information collected through the compliance survey required under paragraph 6) and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high. Monsanto will confer with the Agency prior to adopting any changes.

8) Monsanto shall train its representatives who make on-farm visits with Bollgard II® cotton growers to perform assessments of compliance with IRM requirements. In the event that any of these visits results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its “phased compliance approach,” to promote compliance.

9) Monsanto shall carry out a program for investigating “tips and complaints” that an individual grower or growers is/are not in compliance with the IRM program. Whenever an investigation results in the identification of a grower who is not in compliance with the IRM program, Monsanto shall take appropriate action, consistent with its “phased compliance approach.”

10) If a grower, who purchases Bollgard II® cotton for planting, was specifically identified as not being in compliance during the previous year, Monsanto shall visit the grower and evaluate whether the grower is in compliance with the IRM program for the current year.

11) Beginning January 31, 2005 and annually thereafter, Monsanto shall provide a report to EPA summarizing the activities it carried out under its compliance assurance program

for the prior year and its plans for its compliance assurance program during the current year. Included in that report will be the percent of growers using each refuge option (or combination of options) by region, the approximate number or percent of growers visited on farm by Monsanto, the number of tips investigated, the percent of growers who were not complying with the IRM requirements, and the follow-up actions taken.

12) Monsanto must allow a review of the compliance records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that the names, personal information, and grower license number of the growers will be kept as confidential business information.

d. Insect Resistance Monitoring.

The registration of Cry1Ac and Cry2Ab2 PIPs expressed in cotton is conditioned on Monsanto carrying out appropriate programs to detect the emergence of insect resistance as early as possible. Resistance monitoring programs include: surveying insects for potential resistance and collection of information from growers about events that may indicate resistance. The Agency is imposing the following conditions:

1) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Heliothis virescens* (tobacco budworm) and *Helicoverpa zea* (cotton bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of tobacco budworm and cotton bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. At least 20 specific collection sites must be established in time for the 2005 growing season. Sites must be focused in areas with high risk of resistance (e.g. where adoption is at least 75% of the cotton planted in that county or parish) while overall being distributed throughout the areas where tobacco budworm and cotton bollworm are important pests. The sampling program should be segregated into different sampling regions rather than sampling within each state in which these insects are economic pests.

2) Monsanto must continue to develop and ensure the implementation of a plan for resistance monitoring for *Pectinophora gossypiella* (pink bollworm). The plan shall include provision for conducting annual studies to evaluate any potential change in susceptibility of pink bollworm populations to the Cry1Ac and Cry2Ab2 proteins using the discriminating dose, diagnostic dose, F₂ screen, DNA markers, or other appropriate method. Collection sites must be focused in areas of high adoption, with the goal of including all states where pink bollworm is an economic pest.

3) Beginning January 31, 2005 and annually thereafter, Monsanto shall provide to EPA for review and approval any revisions to its resistance monitoring plan.

3) Monsanto must also follow up on grower, extension specialist or consultant reports of less than expected results or control failures (such as increases in damaged squares or bolls) for the target lepidopteran pests (*Heliothis virescens* (TBW) and *Helicoverpa zea* (CBW), *Pectinophora gossypiella* (PBW)) as well as for cabbage looper, soybean looper, saltmarsh caterpillar, cotton leafperforator and European corn borer. Monsanto will instruct its customers (growers and seed distributors) to contact them (e.g., via a toll-free

customer service number) if incidents of unexpected levels of tobacco budworm, cotton bollworm, or pink bollworm damage occur. Monsanto will investigate all damage reports. See Remedial Action Plans section below.

4) A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by June 30th each year for the duration of the conditional registration.

e. Remedial Action Plans

Specific remedial action plans are required for Bollgard II® cotton for the purpose of containing resistance and perhaps eliminating resistance if it develops. One remedial action plan is for the area where pink bollworm is the predominate pest and the other is for the area where tobacco budworm and cotton bollworm are the predominate pests.

1) Remedial Action Plan for Pink Bollworm

If resistance involves the pink bollworm (*Pectinophora gossypiella*), Monsanto must implement the Arizona *Bt* Cotton Working Group's Remedial Action Plan. Monsanto must obtain approval from EPA before modifying the Arizona *Bt* Cotton Working Group's Remedial Action Strategy.

2) Remedial (Mitigation) Action Plan for Tobacco Budworm and Cotton Bollworm

If resistance involves the tobacco budworm (*Heliothis virescens*) and/or the cotton bollworm (*Helicoverpa zea*), Monsanto must implement the Remedial Action Plan. Any interest in doing that still?] Monsanto must address issues raised by EPA in its review of the Remedial Action Plan by November 15, 2004. Monsanto must obtain approval from EPA before modifying the Remedial Action Plan for Cotton Bollworm and Tobacco Budworm.

f. Annual Reports.

Beginning January 31, 2005 and annually thereafter, Monsanto will provide an annual report to EPA on its Cry1Ac and Cry2Ab2 PIPs expressed in cotton. This report must include, but is not limited to, annual sales (both units sold and estimated acres planted) by state (units sold by county will be made available to the Agency upon request, changes in grower education, the description of grower agreements in place, grower agreements in place, grower compliance with IRM requirements, and insect resistance monitoring results).

This section 3 registration is subject to cancellation under section 6(e) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, if the terms and conditions of this registration are violated, and the company (Monsanto Company) does not comply with the terms and conditions of the registration

Sincerely,

Janet L. Andersen, Ph.D., Director
Biopesticides and Pollution
Prevention Division (7511P)

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 524-522

Send to SIG: check box ☐

This material is:

- ☐ New stamped-accepted label
- ☐ New CSF
- ☐ Notification
- ☐ Final Printed Label
- ☒ Other: Note to file

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: Leonard Cole

Phone: 305.5412 Division: BAPD

Date: 1/16/07

Note to the File for 524-522

December 30, 2006

From: Janet L. Andersen, Director

Biopesticides and Pollution Prevention Division



Decision number 363974 (amendment B90) was withdrawn by the registrant, Monsanto, after EPA had reviewed all the data, held an SAP meeting and made a decision that the data to date did not support the amendment. Because EPA had made a decision, even though a formal letter to the company had not been sent, OPP is not authorizing any refund of the PRIA fee.

In the future, Monsanto will provide additional data that may support the registration amendment, but it will be different data and new request for an amendment will require a new PRIA fee to be paid.